How To Achieve DSCSA Compliance by November 2023

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As the world surges into the new year, pharmaceutical companies that manufacture pharmaceuticals in and/or for the United States seeking to comply with the Drug Supply Chain Security Act (DSCSA) may find themselves scrambling to meet the 27 November 2023 deadline requiring them to track and trace prescription drug products within the supply chain. Congress enacted the 60-page DSCSA in November 2013 as Title II of the Drug Quality Security Act (DQSA) to protect patient safety. That provided the pharmaceutical industry with an outline for achieving "interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States" (**1**). DSCSA compliance enables the US Food and Drug Administration (FDA) to protect consumers from exposure to dangerous drugs that can include counterfeits or diverted, stolen, and contaminated products. The DSCSA also facilitates how the industry manages and executes a drug recall process.

Although the DSCSA was enacted less than 10 years ago, its aspirations toward pharmaceutical traceability date back to the Prescription Drug Marketing Act of 1987 and the addition of 21 CFR Part 203, which lawmakers passed about a decade later to provide additional guidance for the pharmaceutical industry's electronic pedigree laws (**2**). Federal delays have prompted several states to develop their own ePedigree regulations, including California, Florida, Texas, and New York. Outside the United States, countries such as Turkey, India, China, Brazil, Argentina, and South Korea have implemented similar regulations, making pharmaceutical serialization and traceability worldwide initiatives.

In 2013, then-president Barack Obama signed the DSCSA into law. The DSCSA provides a 10-year rollout plan with a unified federal approach, enabling pharmaceutical organizations to implement unique identifiers at a drug's lowest salable unit. Doing so allows organizations to follow a product's life cycle as it moves throughout the supply chain, from manufacturer to dispenser. GS1 created a standardized global-collaboration platform that brings together officials, industry leaders, regulators, academics, and nongovernmental organizations (NGOs) to develop standards-based solutions to address the difficulties of data exchange. The pharmaceutical industry can use that protocol to communicate information for millions of products flowing through the supply chain (**3**).

The COVID-19 pandemic stifled the pharmaceutical industry's progress toward DSCSA compliance until the


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"big three" distributors — Amerisource Bergen Corporation (ABC), Cardinal Health (CAH), and McKesson Corp (MCK) — intervened in 2021. Each of those major players issued supplier letters in 2022, requesting all trading partners to ensure interoperability by November of that year — one year before the DSCSA deadline. In those letters, the big three requested that partners prepare early to account for integration, which requires extensive testing to ensure data integrity in a process that may take several months from start to finish. The supplier letters reiterated legislation that will prohibit distributors from accepting physical shipments that are unaccompanied by matching electronic data transmissions in electronic product code information services (EPCIS) format. Apart from fines, sanctions, and even jail time in extreme cases, supply-chain disruptions are likely to occur if trading partners fail to meet the technical requirements dictated by the DSCSA.

Although numerous pharmaceutical companies have started the process toward achieving DSCSA compliance, many organizations are lagging behind. With the deadline less than a year away, compliance should be considered an urgent matter. To achieve it, companies must incorporate several important steps to ensure successful implementation of serialization and traceability.

Act Immediately

Simply put, for companies that have yet to prioritize DSCSA compliance, the time to do so is now. As stated in one of the Healthcare Distribution Alliance's (HDA's) manufacturer surveys, the integration process for EPCIS interoperability may take weeks or even months. Extensive testing is required to ensure that files are structured correctly and kept free from errors. The big-three supplier letters stated

that if a trading partner is not ready to start testing for EPCIS data transmission, then that company could get placed "at the end of the line" and may not be guaranteed a position to complete testing and meet the deadline. Implementing DSCSA requirements takes collaboration among trading partners in the supply chain. Therefore, organizations need to have internal processes and resources in place while considering the availability of their partners to collaborate on the testing process.

Allocate and Invest in Internal Resources

To achieve EPCIS interoperability by November 2023, pharmaceutical organizations must invest in both capital and personnel while actively communicating with trading partners and service providers. DSCSA compliance is not only a collaborative effort between trading partners, but also among different sectors within an organization. Dedicated personnel should be assigned to manage compliance requirements and communicate internally with other stakeholders.

Success requires a coordinated effort from individuals in leadership, compliance, information technology, and logistics. Decision-makers can prevent a "bottleneck" by authorizing the prompt acquisition of tools necessary to facilitate DSCSA compliance. Company-wide employee training can ensure that stakeholders are aware of new operating procedures that will be affected by DSCSA compliance.

Pharmaceutical organizations must develop and implement an internal infrastructure for using EPCIS, which includes acquiring physical upgrades to capture and store data. Organizations should communicate with contract manufacturers to determine their needs for software and equipment purchase, installation, and testing. Manufacturers should complete line upgrades and have systems in place to capture product identifier data and serialize products at the unit level. In addition, manufacturers will need to ensure that transaction data are successfully formatted into EPCIS files that follow GS1 standards and guidelines. Wholesale distributors need to ensure that they have systems in place to receive and store EPCIS data that can be transmitted to their respective trading partners, including dispensers at all levels (e.g., pharmacies and healthcare systems).

Communicate with Trading Partners and Solutions Providers

Although DSCSA compliance is an individual business decision, significant investments and ongoing interactions with trading partners and service providers are required immediately. Moreover, the COVID-19 pandemic has created significant stress and diverted priorities within the pharmaceutical industry. The pharmaceutical supply chain has a large number of entities that need to achieve DSCSA compliance with a limited number of viable solutions providers. This has created a scarcity of subject-matter experts (SMEs) and challenged the availability of trading partners for collaboration. Obstacles such as those further urge organizations to act fast toward achieving DSCSA compliance.

To meet the 27 November 2023 deadline, trading partners and solutions providers need timely and diligent collaboration. According to the industry's big three distributors, companies should do so at least six months before the official deadline. Every milestone of DSCSA implementation takes time, and establishing connections between manufacturers and wholesale distributors requires significant effort and resources as well.

As suggested by the HDA in September 2020, trading partners should establish a relationship with a service provider that they can include in their ongoing discussions. DSCSA solutions providers are SMEs who facilitate connections between trading partners, enabling manufacturers to establish points of contact with each of their wholesale partners. That means creating tens of thousands of individual connections between trading partners, from manufacturer to wholesaler, or distributor to dispenser.

Don't Expect Further Delays

Throughout the 10-year DSCSA roadmap, the FDA has granted enforcement delays to prevent major supply chain disruptions. In most instances, those discretions were welcomed and required to ensure that the pharmaceutical industry remained on track toward achieving compliance.

However, on 16 November 2021, the FDA held a public meeting in which several pharmaceutical supply chain stakeholders expressed concerns regarding the roadmap for DSCSA compliance. During the meeting, Connie Jung, the FDA's former acting associate director for policy and compliance, urged the industry to "get serious" and focus on achieving compliance. Although the COVID-19 pandemic shifted the industry's priorities and slowed its progress toward data interoperability, further discretion is not expected to happen. The clock is ticking, and the fast-approaching deadline is less than one year away.

References

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3 *About GS1.* GS1: Ewing Township, NJ, 2022; https://www.gs1.org/about.

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