The DSCSA compliance deadline for dispensers has been extended

HERE'S WHAT YOU NEED TO DO NOW

To give dispensers additional time to coordinate compliance efforts with their partners, the U.S. FDA has extended the deadline to March 1, 2016.

Good news! The FDA has extended the deadline for compliance with the Drug Supply Chain Security Act (DSCSA)[1] from November 1, 2015 to March 1, 2016 because some drug dispensers — primarily smaller, independent pharmacies and health systems — need additional time to work with partners on compliance issues.

That said, the deadline is still fast approaching, and dispensers need to act immediately to comply with the new drug tracking, verification, and serialization regulations.

Here are 4 things you should be doing right now to prepare:

1. Talk to your suppliers about T3

Work with your suppliers to evaluate their current capabilities and determine how Transaction History, Information, and Statement (T3) will be provided. Clarify whether suppliers will provide T3 electronically or on paper, and also confirm what specific information will be provided.

2. Begin new process/solution implementation

Plan to have new compliance processes in place well before March 1, 2016, keeping in mind that the timeline for a typical solution implementation ranges from one to three months, depending on supplier readiness.

3. Streamline your receiving workflow

Modify your receiving process workflow to accommodate verification of proper product documentation until DSCSA sunsets in 2023. Allocate time for verification, and use a well-defined process and easy-to-use information system to streamline the workflow.

4. Consolidate your receiving process

Health system pharmacies or pharmacy chains with multiple locations should plan to consolidate the receiving process as much as possible to minimize risk and reduce errors.

1 DSCSA Implementation: Product Tracing Requirements for Dispensers–Compliance Policy (Revised), issued on Oct. 28, 2015

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Axway can help.

Axway's Global Traceability and Compliance solution can help you automate and streamline your workflow to achieve DSCSA Phase 1 lot-level compliance. The solution provides instant connectivity to your suppliers and end-to-end lifecycle management of T3, including:

- Collecting lot-level T3 documentation on every product purchased. Axway's extensive pharmaceutical manufacturer and distributor customer footprint makes it easier to add and validate supplier connections. Axway can instantly verify if we are already connected to your suppliers and provision your environment with stored trading partner profiles.
- Supporting rapid audit and recall response. Our solution stores data in a central system regardless of the inbound format, simplifying the process of responding to an FDA audit. You can be prepared to provide T3 within two business days during suspect product investigations and recalls, and notify the FDA and supply chain partners.
- Retaining and securing data. The solution is deployed as a single instance (not multi-tenant) to mitigate security risks and enable compliant retention of T3 documentation for six years.
- Searching and retrieving records using any captured attribute. Robust reporting capabilities enable search based on any product attribute captured, enabling dispensers to derive more value from data stored in the system.

Why Axway?

Throughout the global supply chain, the top 20 pharmaceutical manufacturers, the major U.S. healthcare wholesalers and distributors, and leading U.S. retail drugstores rely on Axway to reduce the cost and complexity of compliance. What's more, the regulators themselves, including the U.S. FDA, rely on Axway to help manage global traceability initiatives.

Ready to learn more? View our webinar, DSCSA Overview for Dispensers; or download our whitepaper, 5 steps to implementing a successful traceability and interoperability strategy for your pharmaceutical or medical device supply chain.

For more information, visit www.axway.com

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