SYSTECH®
connected solutions by **Markem-Imaje**®

DSCSA

Critical DSCSA compliance software & services

Act now to establish interoperability by the compliance deadline

The final miles one of the DSCSA implementation timeline mandates the implementation of an **electronic, interoperable system** to trace prescription drug products at the package level by **November 27, 2023**. The FDA refers to these mandates as the **Enhanced Drug Distribution Security Requirements** and they impact the entire pharmaceutical supply chain ecosystem: manufacturers, distributors, dispensers, repackagers, 3PLs and their trading partners. Even with UniTrace® deployed, **there are additional steps that you must take for UniTrace to account for certain DSCSA standards**.

DSCSA preparedness: Systech can help account for Enhanced Drug Distribution Security Requirements

Leveraging the UniTrace platform, Systech has developed add-on DSCSA compliance software and related services, including DSCSA product enhancements, configu ation, and testing, to help you achieve compliance. Together, we can help you ensure that endpoint data connections, product registrations, authorized trading partner (ATP) veri cations and record keeping are in place.

Non-compliance: Know the risks!

Regulatory Action: The FDA has the authority to take action against any entity that is not in compliance with DSCSA regulations

Business Disruption: Non-compliance may cause shipment delays or the inability to sell certain products

Reputational Harm: Failure to comply may harm your industry reputation, making it difficult o do business in the future

Legal Liability: Non-compliance may result in lawsuits from your customers. and/or other stakeholders.

Loss of License: In extreme cases, non-compliance may lead to the revocation of licenses or permits that are required to operate in the pharmaceutical supply chain

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1 EPCIS TI/TS

Seamlessly exchange EPCIS-compliant data with trading partners

- ✓ Include product identifier—t ansaction information and transaction statement (TI/TS)—when ownership is transferred
- ✓ Include each product identifier at pa kage level

2 Verification

Provide tools to verify product information, leveraging Systech's Verification outer Service (VRS) solution

- ✓ Verify legitimacy of saleable returns
- ✓ Investigate suspect or illegitimate product
- ✓ Process exceptions
- ✓ Check product status

3 Credentialing

Confi m the entities you do business with are licensed/registered

- ✓ Systech has partnered with Spherity to offer efficient acc editation of all supply chain partners

4 Tracing

Unlock DSCSA tracing via UniTrace platform

- ✓ Provide record keeping and access to the data for six years
- ✓ Assist on saleable returns and product investigations

ACTION REQUIRED
Satisfying the mandatory requirements

In order to satisfy the DSCSA regulatory requirements manufacturers must:

- Establish the interoperable data connections to exchange the EPCIS TI/TS information with their trading partners
- Verify that those trading partners are authorized
- Provide record keeping and access to the data for six years
- Provide all necessary facilities to expedite the response during product investigations using verification and t acing processes.

We've developed these required packages to help you meet the interoperability requirements. **Your systems will not be compliant unless you take these steps.**

DSCSA Software Module Add-On
[required for compliance]

The Systech UniTrace® DSCSA Software Module is designed to help you meet the final FDA DSCSA requirements

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DSCSA Deployment Package
[required for compliance]

Deployment services include configuration, testing, validation and migration

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DSCSA also requires that you complete a full validation. For your convenience we offer this service below.

Full Organization Master Validation Service Package

Master validation plan, user acceptance testing, risk and vendor assessment, summary reports

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With Systech on your side, you can focus on your business while we help your team prepare for the final DSC A hurdle. Don't wait to implement the DSCSA Software Module add-on. Speak with your account representative to schedule your deployment.

Key service benefits

Systech understands the DSCSA's Enhanced Drug Distribution Security Requirements and are here to support you every step of the way. We offer a high-level of personalized attention to help you quickly and efficient y meet your deadlines.

Count on Systech to:

- Offset the burden of this additional compliance workload
- Augment your capabilities with deep DSCSA compliance expertise
- Navigate you through the required steps
- Coordinate, perform and validate interoperability before the go-live date
- Compile documentation for proof of compliance

With the deadline approaching, demand for Systech services will be high. Reserve your spot in the queue today!

Deployment and validation services will be scheduled on a first come first serve basis.

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GET CONNECTED

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