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Drug Supply Chain Security Act (DSCSA) Interoperability Mandate

The Final Leg of DSCSA Compliance
Are You Prepared?

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DSCSA - Where We Are Today

The pharmaceutical industry is in the final stage of the Drug Supply Chain Security Act (DSCSA) implementation . Enacted by Congress in the fall of 2013, DSCSA outlines the steps to achieve interoperability, electronic tracing of products at the package level, and to identify and trace prescription drugs as they are distributed in the United States . The primary purposes of DSCSA compliance include quickly verifying the authenticity of a prescription drug, enhancing drug recall processes, and improving the detection and interception of illegitimate products in the supply chain .

With patient safety as its core objective, DSCSA protects consumers from exposure to dangerous drugs, including counterfeits, diverted, stolen, and contaminated products, as well as facilitate how the industry manages and executes the drug recall process . DSCSA compliance also serves as a defense from intentional efforts by organized crime and state sponsors to monetize and cause harm by attacking the supply chain .

Pharmaceutical manufacturers use serialization systems to track and trace prescription drugs throughout the entire supply chain to achieve DSCSA compliance. With serialization systems, manufacturers can easily identify every product by utilizing a unique serial number . Traceability adds visibility from a material's origin to its delivery and offers real-time insights into a serialized product's history, including chain of custody.

The Updated DSCSA Deadline - Nov 27, 2024

In October 2023, the FDA granted the pharmaceutical industry a much-needed one-year enforcement discretion period. The decision to delay DSCSA's enforcement was made after several stakeholders had expressed concerns over readiness and the need for clarity and flexibility to ensure trading partners can continue to move product through the supply chain when the requirements take effect. The intention is to avoid any impact on the supply of patient medication.

This deadline marks the culmination of years of industry preparation. Non-compliance can lead to severe consequences, including fines, sanctions, and possible criminal charges. The industry must prioritize and focus on adherence to regulations.

The Last Phase of DSCSA Requirements – Interoperability

DSCSA's unified federal approach will implement unique identifiers at a drug's lowest salable unit, allowing the industry to have visibility into a product's lifecycle as it moves through the supply chain, starting with manufacturers and ending at the dispenser. In addition, by utilizing a standardized protocol created by the industry-standard group, GS1, the pharmaceutical industry can communicate information regarding millions of products that flow through the supply chain.

Until November 27, 2023, wholesale distributors, dispensers, and repackagers can use either paper-based or electronic-based methods to provide transaction history, transaction information, and transaction statements to subsequent purchasing trading partners as long as the selected method allows the information to be exchanged in a manner that complies with outlined requirements.

Simultaneously, manufacturers can use electronic-based methods to provide transaction history, transaction information, and transaction statements to subsequent purchasing trading partners. But a manufacturer may provide transaction history, transaction information, and transaction statements in a paper format if the subsequent purchaser is either a State licensed health care practitioner authorized to prescribe medication; or a licensed individual who dispenses product in the usual course of professional practice and is under the supervision or direction of a licensed prescribing health care practitioner.

The Last Phase of DSCSA Requirements – Interoperability (Continued)

However, that all changed with the November 2023 deadline . Beginning Nov 27, 2023, electronic-based approaches are generally required to be used among all trading partners to meet the enhanced drug distribution security requirements . Therefore, on that date, trading partners are required to use secure, interoperable, electronic approaches to:

- Exchange transaction information that includes package level product identifiers for each package included in transactions and transaction statements
- Verify products at the package level
- Promptly respond with the transaction information and transaction statement for a product in the event of a recall or investigation
- Facilitate the gathering of transaction information for a product going back to the manufacturer in the event of a recall or for investigations
- Accept saleable returns under appropriate conditions

Enforcement of DSCSA to begin on Nov 27, 2024 at the end of the one year stabilization period

EPCIS Now Required

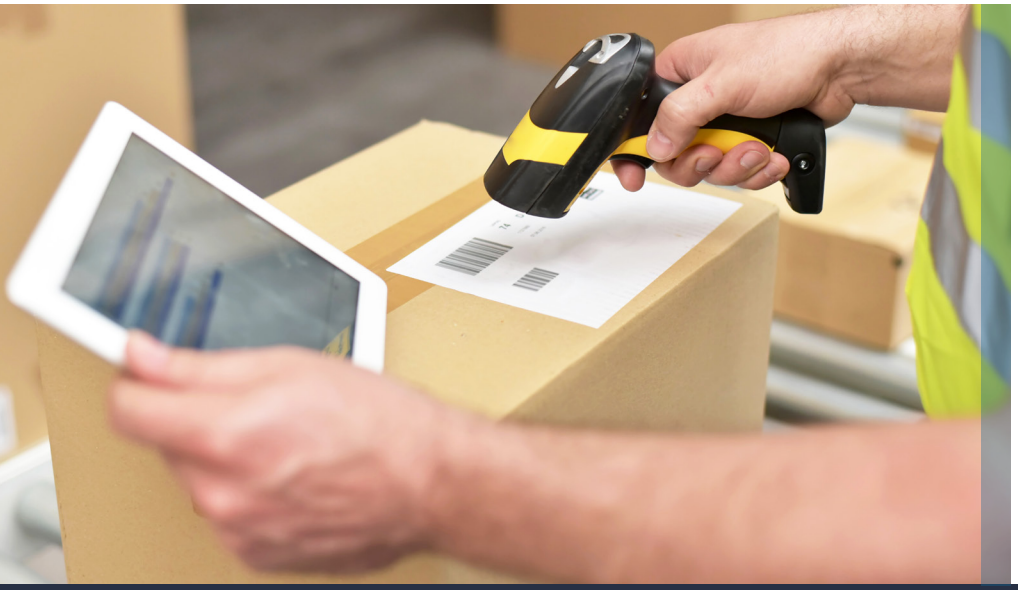
Per DSCSA requirements, data for pharmaceutical products must be shared amongst trading partners, more specifically as the product changes ownership during its lifecycle in the supply chain. In the US and many other nations, the pharmaceutical industry has adopted EPCIS standards for automatic data communication amongst partners in the supply chain.

EPCIS is a GS1 standard that enables trading partners to share information about the products' physical movement and status as they travel throughout the supply chain – from business to business and ultimately to consumers. Due to an overly complex distribution network, it is not uncommon to have products change ownership over ten times during their lifecycle. This becomes particularly valuable when a product may have multiple owners before being dispensed to a patient, and there is a compelling need to have chain-of-ownership and custody data.

Interoperability Status

During the annual Traceability Seminar in November 2021, the Healthcare Distribution Alliance (HDA) disclosed the results of its recent supplier survey around data interoperability progress, which were far from encouraging, considering the legislation was two years away from the ultimate deadline at that time .

In this study, 54% of respondents were manufacturers, and 46% were distributors. Amongst all participants, only 37% indicated they were actively interoperable with approximately 1-5% of their trading partners. Furthermore, a major distributor, a member of the Big Three family (the three largest pharmaceutical distributors in the US territory), indicated concerns around data quality and failures caused by EPCIS/ DSCSA syntax or semantics issues when receiving files from trading partners. These issues were present amongst third-party logistics providers (9% failure rate) and manufacturers (37% failure rate).



These results speak to the necessity and urgency of comprehensive interoperability testing, ideally at least one year prior to November 2023.

Interoperability Testing is Crucial

To successfully meet the November 27th, 2024 enforcement deadline, trading partners and solutions providers need to collaborate to verify that the EPCIS data can successfully be passed and, if necessary, modified and shared due to routine supply chain procedures such as breaking down pallets for order fulfillment .

Even with guidelines in existence, file formats for sharing data can vary from company to company, making it critical that manufacturers test connections with all trading partners to confirm interoperability . In addition, extensive testing is required to ensure files are properly structured and all errors are corrected before pushing to production . As a result, the integration process for EPCIS interoperability may take weeks or even months .

Every milestone of DSCSA implementation takes time, and as already experienced during the first phase of DSCSA implementation (LOT level tracking via ASNs), establishing connections between manufacturers (including contract manufacturers and repackagers) and wholesale distributors requires significant efforts, resources, and time.

5 Steps to Take Now to Prepare for the DSCSA Deadline

1. **Make Comprehensive Interoperability Testing a Priority -** Interoperability testing is a complex and timely process. It is necessary to start your testing journey immediately to meet deadlines.

2. **Communicate With Trading Partners and Solutions Providers -** Trading partners should establish a relationship with a service provider and include the service provider in their ongoing discussions. DSCSA solutions providers are subject matter experts who facilitate connections between trading partners. This process will require each manufacturer to establish a point of contact with each of its wholesale partners. When put in an industry-wide perspective, this means creating tens of thousands of individual connections between trading partners at the manufacturer to wholesaler level. The same scenario applies to wholesale distributors connecting to tens of thousands of downstream dispensers.

3. **Do Not Forget your 3PL-** The first step in the connection setup will happen with your 3PL. This has to precede the connection setup with your wholesaler and will affect your readiness timeline.

4. **Evaluate the Support You Receive From Your Serialization Provider - I**n the beginning stages of DSCSA implementation, many organizations rushed to partner with a serialization provider without much due diligence or knowledge of requirements and procedures. The number of service providers was limited, and clients had fewer options. This led to many organizations signing standard 3-year contract agreements with optional renewal terms on the fourth year onwards. Unfortunately, it is not unusual to hear about unsatisfactory customer experiences with some larger serialization providers. Some common complaints are constant changes in project management personnel, lengthy wait periods to receive responses for support requests, and increasingly elongated ETAs to resolve technical issues. Carefully consider whether your service provider can support your requests in due time.

5. **Be Prepared and Don't Expect Further Industry Delays-** While over the past eight plus years, there have been many enforcement delays, do not expect further industry enforcement discretions. Connie Jung – the FDA's Associate Director for Policy and Compliance – recently urged the industry to "get serious" and focus on achieving DSCSA compliance. The clock is ticking, and the November 2023 deadline is fast approaching.

Covectra – The Premier Serialization Solution for Pharmaceutical Brands

Pharmaceutical manufacturers and product brands are racing to adopt serialization and track and trace solutions to ensure efficient product traceability, better monitor their supply chains, reduce product diversion, and ensure DSCSA compliance . These manufacturers and contract manufacturers/packagers are facing increasing pricing and margin pressures to meet the stringent regulations for implementing serialization and the growth in the number of packaging-related product recalls .

AuthentiTrack Enterprise

Ideal for companies that have multiple lines within their facility that need to be serialized, the AuthentiTrack Enterprise solution encompasses the site, line, packaging units — and the devices within the packaging unit — to provide a complete serialization operation at the plant level . The AuthentiTrack Enterprise solution offers connections to your ERP system for the automated exchange of product-related master data required for serialized product . After the merchandise is packaged and shipped, a connection to the AuthentiTrack Cloud provides serial number provisioning and an event history repository .

AuthentiTrack Prime

AuthentiTrack is a complete product serialization solution (Levels 1-3 and 5) designed to make it easier for growing manufacturers to meet compliance needs, maximize uptime, and ensure product integrity with semi-automatic or manual, low-volume packaging operation . Designed to be up and running within hours, AuthentiTrack Prime is a standalone system and can be placed next to the production line without more complex integration . It also can be easily transported and set up in new locations and is very competitively priced .

Covectra – The Premier Serialization Solution for Pharmaceutical Brand(Continued)

Covectra's affordable, flexible, easy to use serialization solutions provide benefits beyond regulatory compliance and safeguarding drug supplies, leveling the playing field for smaller players and providing unprecedented insight about inventory levels, shipping logistics, and supply/demand data. Covectra's serialization systems can also provide timely and complete data for post-facto analysis of supply chain issues.

Role of Services

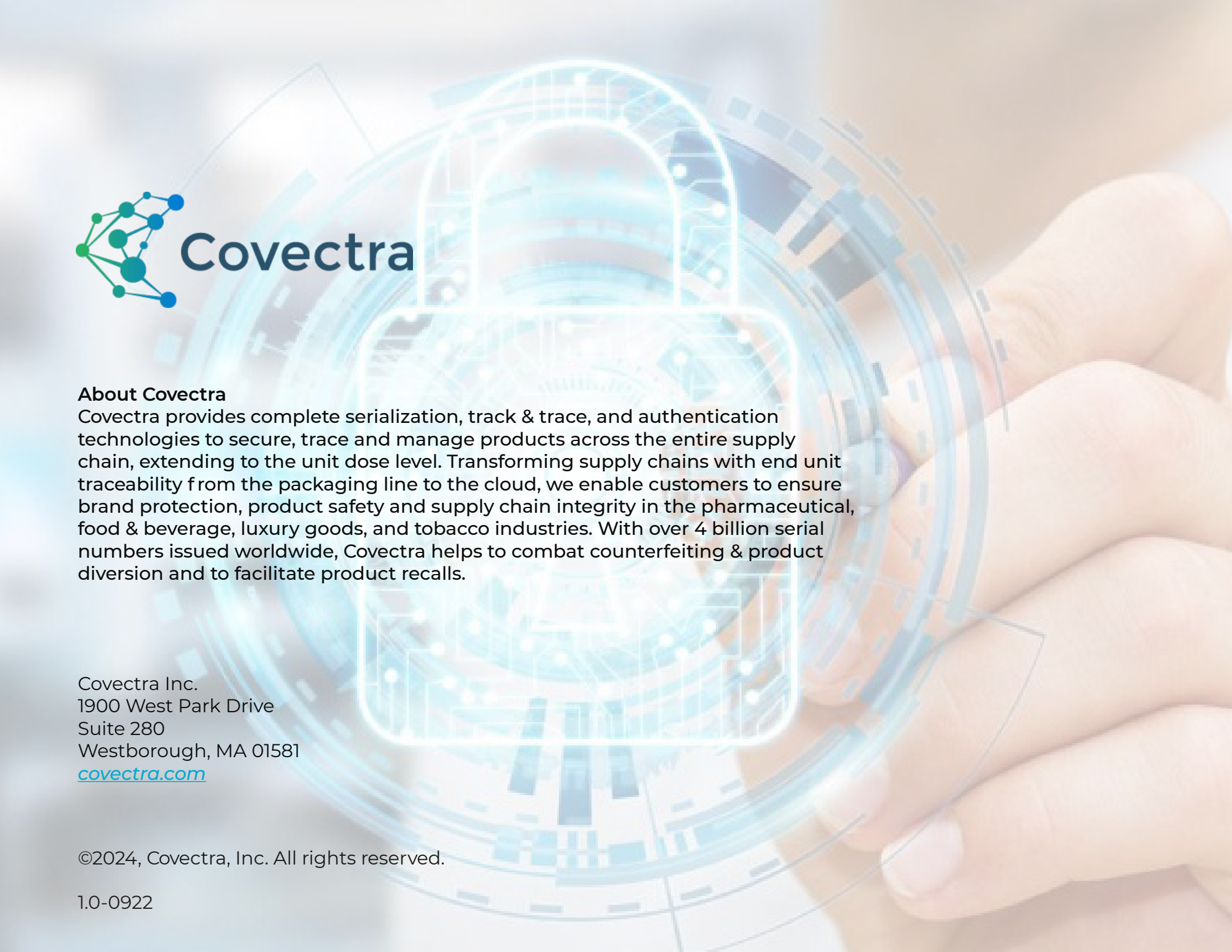
Covectra can be your in-house resident expert for serializing your product. We offer IT and engineering services to ensure your serialization solution is dependable, efficient, secure, monitored, up to date with GS1, DSCSA compliant, and runs consistently in day-to-day operations.

Financing Options

Covectra's flexible financing options lower up front costs, enabling small companies to get a start on their serialization journey quickly and affordably .

Superior Support

Covectra's team of experts supports clients at every step of the serialization process from concept, design, development, installation, to implementation and proper record keeping. Our client's success is our priority! We focus on small companies who do not have the budget to fund a complete serialization team, as well as larger companies that are not being properly supported by their existing serialization provider.



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About Covectra
Covectra provides complete serialization, track & trace, and authentication technologies to secure, trace and manage products across the entire supply chain, extending to the unit dose level. Transforming supply chains with end unit traceability from the packaging line to the cloud, we enable customers to ensure brand protection, product safety and supply chain integrity in the pharmaceutical, food & beverage, luxury goods, and tobacco industries. With over 4 billion serial numbers issued worldwide, Covectra helps to combat counterfeiting & product diversion and to facilitate product recalls.

Covectra Inc.
1900 West Park Drive
Suite 280
Westborough, MA 01581
covectra.com

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