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Navigating the new U.S. serialization requirements for pharmaceutical logistics success

Introduction

The Drug Quality and Security Act (DQSA) was enacted by the U.S. Congress on November 27, 2013, introducing serialization requirements for drug products to enable more effective traceability, with ramifications for pharmaceutical companies' logistics needs when operating in the U.S.

The next phase of the Act, Title II, is due to come into force at the end of 2023. According to the U.S. Food and Drug Administration (FDA), the enhanced system will:

- Enable secure tracing of products at the package level.
- Use unique product identifiers (UPIs) to verify products at the package level.
- Enable prompt response to suspect and illegitimate product.
- Improve the efficiency of recalls.

The goal is to enhance the FDA's ability to detect and remove counterfeit, stolen, or contaminated prescription drugs from the domestic market. In doing so, the FDA hopes to further safeguard consumers from exposure to potentially harmful drugs.

However, these new requirements pose a number of challenges for every company along the pharmaceutical and biotech supply chain – not just manufacturers, but third-party logistics (3PL) providers, wholesalers, and dispensers, too. In addition to having the packaging and labeling equipment in place to enable track and trace, additional logistical infrastructure is required to effectively monitor and follow each pack throughout its journey from the production line to the patient.

How can companies ensure that they have the right supply chain solution to meet future track and trace compliance needs?

In this white paper, we will explore:

- The provisions of the new FDA requirements and the reasons for the new legislation.
- The benefits of the new requirements not just for pharmaceutical companies' brand reputation, but ultimately for patient safety.
- How pharmaceutical companies can ensure they remain compliant with changing U.S. requirements.

History of serialization

The rise of counterfeit drugs and concern over patient health led to the implementation of serialization requirements with the Drug Supply Chain Security Act (DSCSA), Title II of the DQSA, in 2013. The DSCSA regulations were the start of a phased implementation of comprehensive serialization, starting with lot-level traceability in 2015, and ending with the upcoming introduction of unit-level track and trace, in force from November 2023.

Together, the DQSA and the DSCSA regulate the logistics of pharmaceuticals in the United States. The DQSA established a framework for a national system of track and trace for prescription drugs, while the DSCSA built on that framework by setting out specific requirements for pharmaceutical supply chain security. The two titles are interconnected and work together to create a more secure and transparent pharmaceutical supply chain.

The impact of serialization on the supply chain

FDA DSCSA serialization requirements

The DSCSA mandates that manufacturers, repackagers, wholesale distributors, and dispensers of prescription drugs in the U.S. must implement an electronic system for tracking and tracing prescription drugs as they move through the supply chain.

These serialization requirements cover the aspects outlined below:

- **A unique product identifier (UPI):** Prescription drug products must be serialized with a UPI that includes the national drug code (NDC) in the form of a global trade item number (GTIN), a serial number, the lot number, and the expiration date. The UPI must be in both a machine- and human-readable format on each package and homogeneous product case.
- **Verification:** All trading partners in the supply chain, including manufacturers, wholesalers, and dispensers, must verify the serial numbers of the prescription drugs they receive. They must also maintain records of the transaction information, including the lot number, transaction date, and the name and address of the trading partner from whom they received the product.
- **Notification:** Manufacturers, wholesale distributors, and dispensers must notify the FDA and their trading partners within 24 hours if they discover that a product they have received or distributed is suspect or illegitimate.

The November 2023 deadline for DSCSA compliance requires mandatory complete unit-level traceability. The goal of these changes is to allow for interoperability between trading partners for data relating to the exchange, verification, and tracing of pharmaceutical products. The changes require all trading partners to securely, interoperably, and electronically:

- Exchange transaction information (TI) and transaction statements (TS). The TI must include the product identifier at the package level.
- Verify the product identifier on a package or sealed homogeneous case, including a standardized numerical identifier.
- Trace and facilitate the provision of TI and TS in response to a request. These systems must also be able to promptly gather the necessary information to produce the TI for each transaction going back to the manufacturer to accept saleable returns and associate them with the TI and TS for that product.

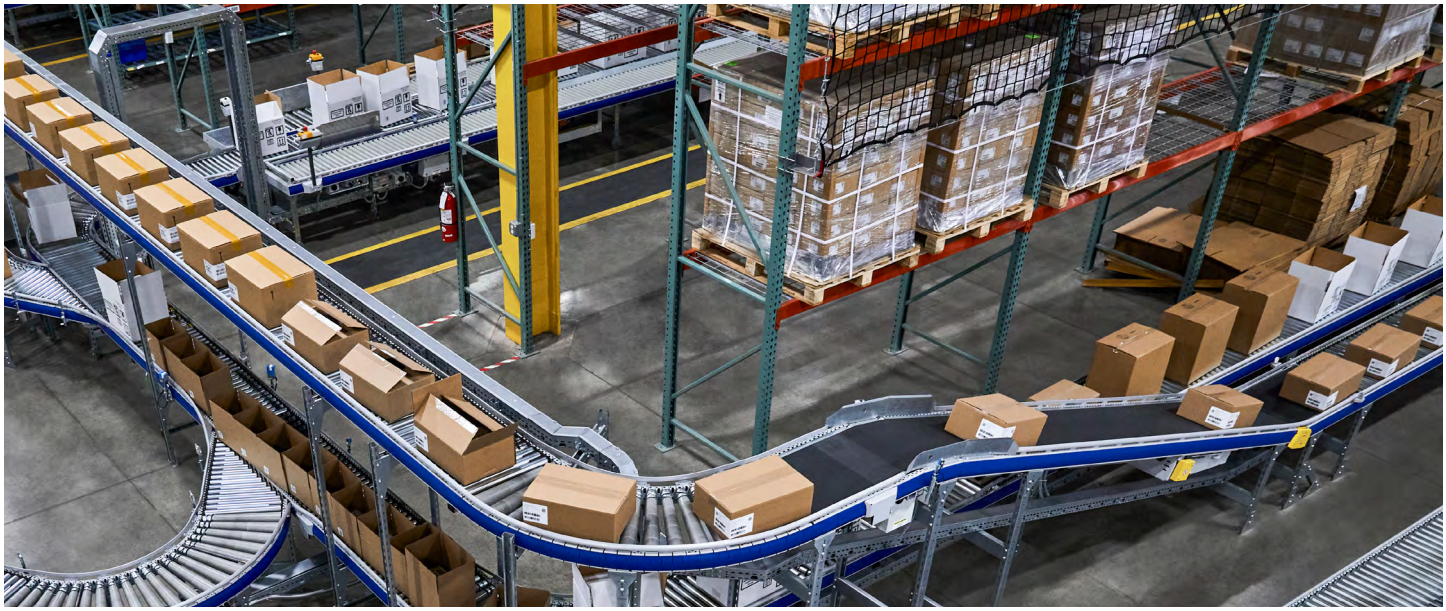
The phased approach to DSCSA regulations has given companies time to implement these changes. Nevertheless, the integration of new technologies, systems, and processes is a challenge that companies need to address to be compliant.

Serialization challenges faced by pharmaceutical companies

The challenges faced by pharmaceutical companies when implementing the latest serialization regulations vary from technical and operational, to financial hurdles.

Technical challenges

The technical complexity of the latest serialization changes is a major challenge for companies. The latest serialization deadline requires the implementation of new systems and technologies, such as barcode scanners, software platforms, and databases. These systems must be integrated within existing IT infrastructures, which can be a complex and time-consuming process. The IT infrastructures used by these companies can often be outdated, adding further difficulties when trying to integrate them with new technology.



Operational challenges

Operations and processes need to change to incorporate the latest serialization needs – such as labeling, packaging, and distribution. Aggregation, a huge benefit to transacting at the package level, has proven to be quite challenging for some manufacturers. Ensuring that all processes and systems are compliant with the new exchange, verification, and tracing regulatory requirements can be a significant undertaking for companies.

Financial challenges

The new equipment, software, and staff needed to implement the latest serialization regulations can be expensive. Additionally, the expenses do not stop after software and equipment are installed – ongoing maintenance and support will be necessary to keep serialization technologies, systems, and processes in working order, which will require further financial investment.

Serialization challenges faced by pharmaceutical companies

Integration challenges

A major requirement of DSCSA regulations is to have interoperable systems. Companies may face challenges integrating their serialization systems with those of their trading partners. There is also the issue of confidential information that needs to be protected while sharing serialization information to give trading partners access to their data without compromising wider company or external partner data. Each partner is likely to be using a proprietary portal to ensure that systems are compatible and to minimize the risk of confidential information falling into the wrong hands. This requires close collaboration and coordination to ensure that all parties are able to share the appropriate data and comply with regulatory requirements.

The final steps to implementing serialization in November 2023 will require a significant investment of time, money, and resources. Companies must be on track to address the technical, operational, and financial challenges that arise, and work closely with their trading partners and regulators. Being well prepared for the rollout of full serialization is a necessary investment for pharmaceutical companies to ensure patient safety and regulatory compliance.

How does serialization affect stakeholders?

Numerous stakeholders in the supply chain are significantly impacted by the serialization of the pharmaceutical industry. The changes implemented will have distinct effects throughout the supply chain, from manufacturers to patients.

Manufacturers

Serialization presents both challenges and opportunities for manufacturers. Becoming serialization compliant may require manufacturers to modify their production lines to integrate new equipment and processes, which can disrupt production schedules and require additional investment. These costs may include equipment upgrades, software development, and training for employees.

The new regulations will mean manufacturers have to manage the large amounts of data generated from serialization. This data must be properly managed and stored, and requires robust data management systems and infrastructure to ensure accuracy, security, and accessibility. These data management systems are also vital to the quality control tracking of UPIs. Any errors or discrepancies in UPIs and the database housing them can result in product recalls, which can damage brand reputation and result in financial losses.

Although serialization requires the manufacturer to make adaptations, it also offers benefits, such as improved supply chain visibility and the ability to track products from production to distribution. These help manufacturers combat counterfeiting and protect their brand reputation while enhancing consumer trust and loyalty.

3PLs

3PLs generally do not "own" a drug product and therefore are not obligated by the DSCSA to generate, transmit, or receive the serialization transaction documents.

However, they are included in the definition of "Trading Partners." This means they are required to verify the authenticity of received serialized products, including checking the UPI and transaction history of each product, which is a significant operational challenge. They must comply with regulatory requirements for handling, storing, transporting, and ensuring that their process and controls maintain the integrity of the UPI. This all requires additional processes and systems to be put in place, which can be complex and may require additional staff training. To support manufacturers effectively as trading partners, 3PLs must invest in new software, hardware, and methodologies to support serialization.

How does serialization affect stakeholders?

Wholesalers/dispensers

As owners of the products, both are responsible for verifying the authenticity of the products they receive. This is a crucial part of their workflow and impacts them across their entire network: national and regional distribution centers, pharmacies, hospitals, and even clinics that dispense to patients. Verification requires checking TI and TS when the product is initially received at any of their facilities. This can add time to the process, but it helps to ensure that patients are ultimately receiving safe and legitimate pharmaceuticals. Compliance with the DSCSA regulations for handling and dispensing serialized products may require additional staff training and infrastructure upgrades to maintain the integrity of UPIs, but it also creates benefits.

One such benefit comes from improving inventory management. Serialization improves the identification and tracking of products and reduces the risk of errors and discrepancies. This also helps combat the proliferation of counterfeit drugs as wholesalers and dispensers can verify the authenticity of a product, improving patient safety. The increased control of inventory management also reduces the risk of medication shortages or stockouts that can impact patient care.

Patients

Serialization makes patients the main beneficiaries of the system. Enhanced traceability through the supply chain helps to ensure that patients receive genuine and safe pharmaceutical products. This supply chain visibility also provides greater transparency while increasing trust between healthcare providers and patients.

Serialization solutions and technologies

Multiple serialization technologies are available to companies to help them ensure compliance with fast-changing legislation. When choosing a solution, it is essential to consider the specific needs of a company and product, as well as the regulatory requirements of the market. Various serialization technologies could allow for DSCSA-compliant UPIs to be attributed to pharmaceutical products. However, linear and GS1 DataMatrix barcodes are predominant in the U.S. and not many manufacturers have adopted technologies such as RFID tags. Cost, complexity, and a lack of proven pedigree have suppressed their uptake across the industry in favor of established solutions.

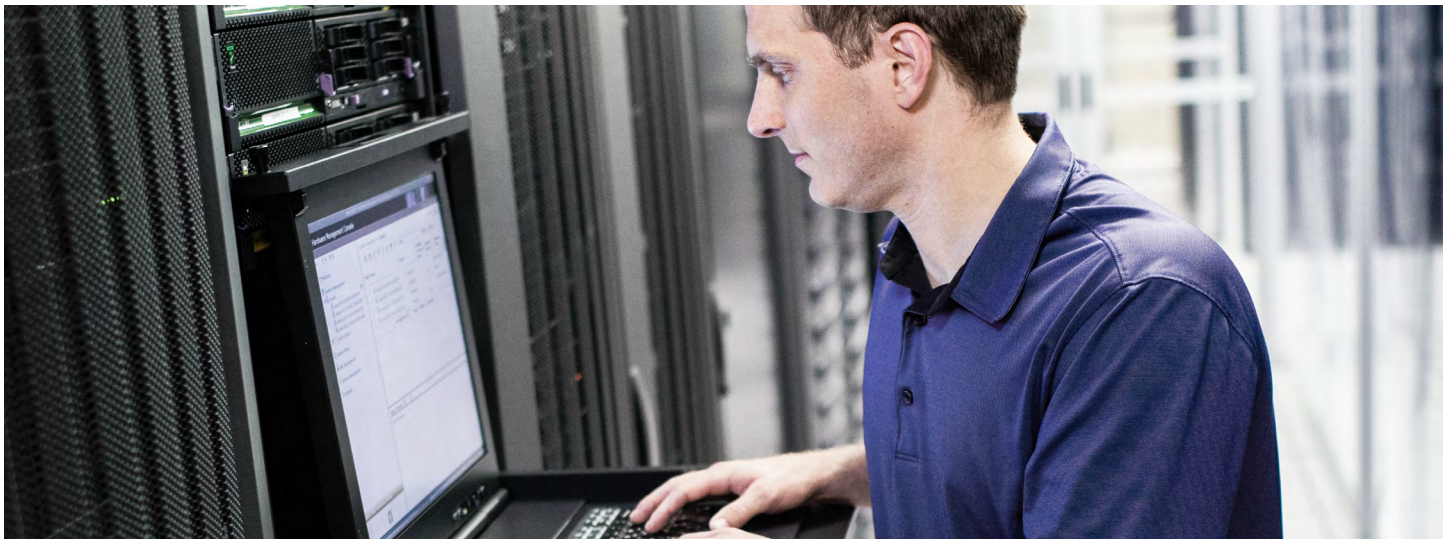
ICS is ready for the changes

Since 1997, ICS has partnered with pharmaceutical manufacturers to deliver customized healthcare logistics solutions that improve the quality and efficiency of their supply chains. ICS is a global 3PL provider and strategic partner that offers expanded, integrated logistics solutions designed to support pharmaceutical manufacturers and cell and gene therapy innovators regardless of the size of their operation or where they are in the commercialization journey. We align supply chain strategy to your business goals to deliver tailored healthcare logistics solutions that increase supply chain efficiency, maximize return on investments, and enhance patient care.

Our system architecture has been compliant with DSCSA well in advance of the requirements and we support manufacturers with their DSCSA tracing obligations. Our deep experience and knowledge have shaped a suite of scalable solutions for a secure supply chain including:

Secure and interoperable data records

We store and maintain all data required for our 3PL DSCSA obligations, track and transmit data at the package level, and our interoperable system is integrated with the majority of data serialization providers utilized by our clients and their customers.



Inbound/outbound services

Informed by years of continuous improvement, our 3PL serialization process supports inbound receipt of serialized products and data via electronic product code information services (EPCIS), aggregated shipment receipt and verification, receipt confirmation, and inbound exception handling and reconciliation. For outbound shipments, we scan, verify, aggregate, and send EPCIS data to downstream partners as well as submitting a copy to the manufacturer's DSCSA repository. We are actively working to prepare for reconciling outbound exception handling that may occur with downstream partners. Tracking products at the package level and transmitting data since 2017, both inbound and outbound, has given us the required experience to meet the upcoming challenges.

ICS is ready for the changes

Customer access to DSCSA documentation

Through a secure portal, ICS offers our manufacturer customers access to TH, TI, and TS under the current requirements. Through a similar portal, we will soon offer TI/TS at the package level to meet the upcoming regulations for those unable to deploy interoperable systems.

A diverse manufacturing reach

ICS delivers logistics solutions that meet the needs of all types of manufacturers, streamlining logistics processes and increasing speed to market – offering both traditional 3PL distribution and title model distribution.

Scalable solutions across all temperature ranges

Our experience and knowledge have helped to shape a suite of scalable solutions designed to meet a variety of serialization needs. From a company commercializing their first drug to larger manufacturers, our solutions are flexible in meeting their needs.

We have also developed unique serialization expertise in supporting manufacturers who require ultra-low and even cryogenic storage conditions.

The role of serialization in the future of the pharmaceutical industry

As the FDA DSCSA phase II deadline of November 2023 arrives, companies will need to know that their logistics partners are ready and compliant. Aside from regulatory penalties and operational challenges, non-compliance can also cause costly delays at the expense of patients and damage the company's reputation and brand. Partnering with a 3PL provider that has already implemented these serialization necessities will allow companies to reap the benefits of serialization across their supply chain.

Serialization will continue to play a critical role in shaping the future of the pharmaceutical industry, boosting efforts to ensure patient safety, and preventing the spread of counterfeit drugs. As new technologies continue to emerge, serialization systems will need to adapt and evolve to keep pace with changing regulatory requirements and supply chain dynamics. The pharmaceutical industry will need to continue to invest in serialization solutions and technologies to meet these challenges and ensure the safety and efficacy of their products.

If you are looking for a 3PL provider that is DSCSA-ready and has deep experience and knowledge in scalable solutions for a secure supply chain, contact us now to start a conversation.

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