Dear US Dispensers,

The US DSCSA regulations will become active very soon. You have about 12 months to comply with the “complete traceability” requirements.

**Date of effectiveness: November 27, 2023!**

Manufacturers and Distributors have been working in compliance for the past several years. If you are a little behind, this guide is the right compliance companion for you.

**Please read on.**
**DRUG SUPPLY CHAIN SECURITY ACT TIMELINE**

**January 1, 2015**
Transactional Information Provided by Manufacturer, Wholesaler and Repackager

**May 1, 2015**
FDA Enforcement Discretion Ends

**July 1, 2015**
Transactional Information Accepted by Dispensers

**November 1, 2015**
FDA Enforcement Discretion for Pharmacies and Dispensers Extended to March 1, 2016

**2014**
- **State Preemption**

**2015**
- **Rackagers Serialize**
- **Federal Licensure Standards for Distributors Raised**
- **Manufacturers Serialize**
  - FDA has provided Enforcement Discretion to the Manufacturers until November 27, 2018

**2016**
- **Wholesaler Accept/Sell Serialized Product and Verify Serialized Number on Saleable Returns.**
  - FDA has provided Enforcement Discretion to the wholesalers until November 27, 2020
- **Dispensers ONLY Accept Serialized Product**
  - Wholesalers Verify Product Identifier Before Redistributing Returns

**2017**

**2018**

**2019**

**2020**

**2021**

**2022**

**2023**

Activities for Compliance:

1. Getting all GS1 identifiers established and reviewed. All master data (GTINs, material information, trading partners, lot #s, etc.) in place. 
   Notes: Allow sufficient time, and enlist experts to help out with this task. These can have deep transactional and regulatory reporting impact.

2. Streamline processes.
   Notes: Understand stakeholders, business impact on existing processes and defining to-be processes.

3. Aggregation capabilities set up and tested. Include exceptions, reporting, tracking.
   Notes: Most exceptions occur in handling overage/underage, unpacking, and repacking transactions.

4. Work on EPCIS message exchange for various levels of hierarchy.
   Notes: This is arguably the one area where boring, technical expertise is needed.

5. Test with distributors and dispensers. Try out lookup directory and reporting modules.
   Notes: Start by Jan/Feb 2023 to allow distributors some time to provide feedback and tweak processes.

6. Test with greater volume and move to production.
   Notes: Testing with greater volume indicates if your solutions and processes are scalable to production-grade data.

7. Live in production.
   Notes: No later than August 2023 to allow at least two months of live information exchange.
The regulations (distilled for easy understanding):

- **Deadline:** Nov 2023
- **Impacted:** Manufacturers, Distributors, Wholesalers, 3PLs and Dispensers (e.g., Pharmacies)
- **Key requirement:** Interoperability to enable:
  - Product Identification
  - Product Tracing
  - Product Verification

- 3Ts to be transmitted electronically to subsequent authorized trading partners before shipment/change of ownership
- EPCIS needed for transmitting the information within Supply Chain
- Any suspicious products must be reported to FDA (or other controlling entity) within 24 hours
- Record retention: 6 years
- No central repository
- Selectable returns to be also reported (no need for Dispenser to send data)

Areas where you may need expert help:

At 3Keys, we focus only on Serialization and Track & Trace. Over the past 7 years, having experience since start of track and trace in pharma, we find the following capabilities are most sought after by manufacturers and distributors:

- Various regulatory reporting and understanding of regulations
- Business benefits of serialization
- What others are doing in the respective industry
- Defining Roadmap on future compliance, another market/region regulations, etc.
- Identification of the different stakeholders impacted by the regulations in supply chain.
- Business impact analysis on the existing business processes
- Defining to be processes
- Helping clients with project planning and management activities
- Help with collecting all required GS1 identifiers
- Integration to implement exchange of required data in EPCIS format with business partners upon change of ownership

**Product Identification:** NDC, Batch Number, Expiry Date, Serial Number

**Product Tracing:** “3Ts”:
  - Transactional Information
  - Transactional History (eASN to replace this requirement)
  - Transactional Statement

**Product Verification:** on item level, to consider aggregation if available
3KEYS GmbH is a leading global Serialisation and Track & Trace consulting company. We deliver Serialisation and Track & Trace projects worldwide across industries using a vendor-agnostic approach.