

US DSCSA COMPLIANCE GUIDE, FOR US DISPENSERS

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Dear US Dispensers,

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

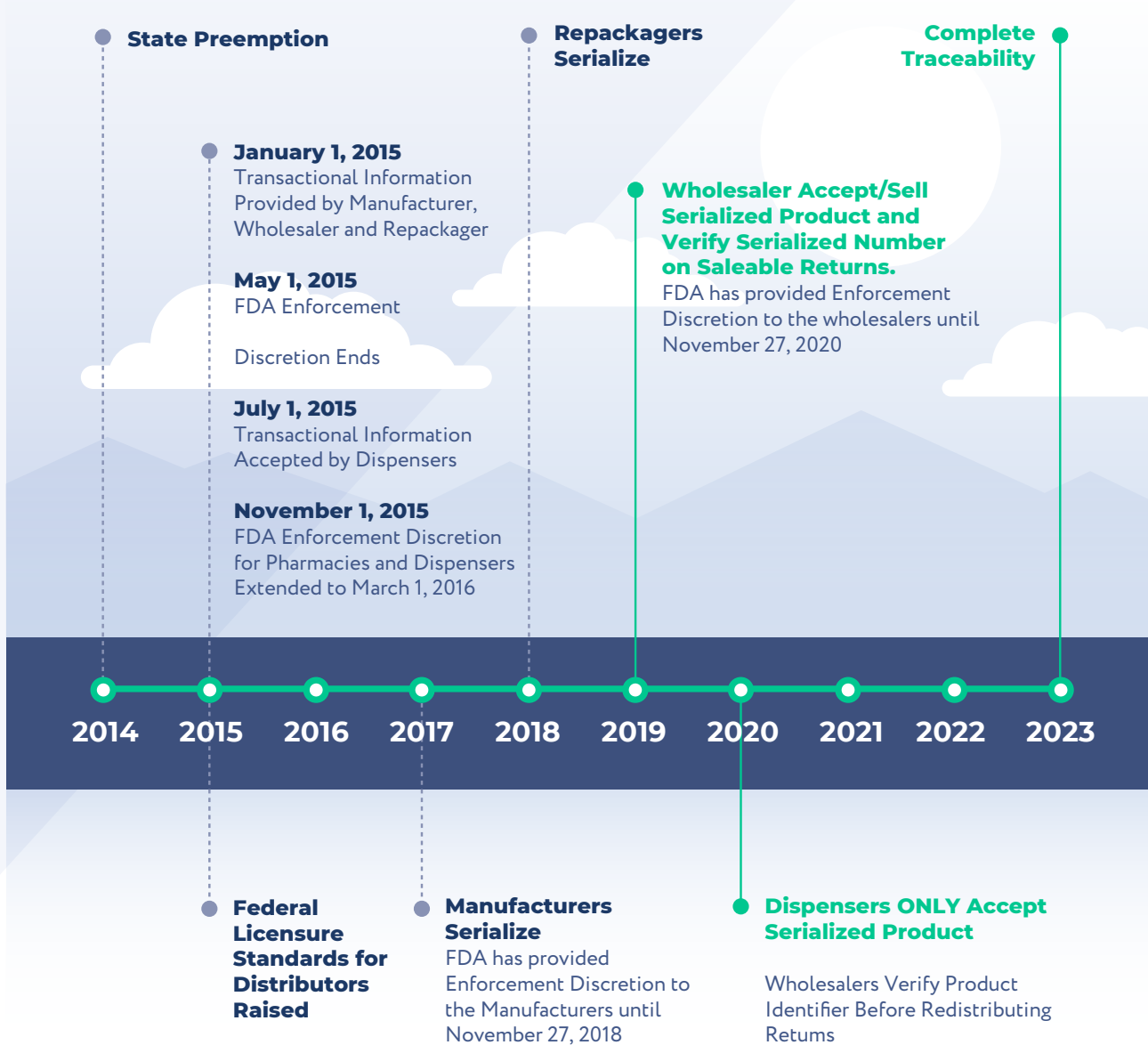
Date of effectiveness: November 27, 2023!

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. 

Timelines:

DRUG SUPPLY CHAIN SECURITY ACT TIMELINE



Activities for Compliance:

Step	Start	Notes / Comments / Considerations
1	Getting all GS1 identifiers established and reviewed. All master data (GTINs, material information, trading partners, lot #s, etc.) in place.	Allow sufficient time, and enlist experts to help out with this task. These can have deep transactional and regulatory reporting impact.
2	Streamline processes.	Understand stakeholders, business impact on existing processes and defining to-be processes.
3	Aggregation capabilities set up and tested. Include exceptions, reporting, tracking.	Most exceptions occur in handling overage/underage, unpacking, and repacking transactions.
4	Work on EPCIS message exchange for various levels of hierarchy.	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.	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.	Testing with greater volume indicates if your solutions and processes are scalable to production-grade data.
7	Live in production.	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

- ✔ **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

- 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
- Seleable 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

TRACK AND TRACE EXPERT AT YOUR SERVICE

Who we are

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.



CONSULTING
PRODUCT DEVELOPMENT
SUPPORT