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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 just about 12 months to be compliant with the **"complete traceability"** requirements.

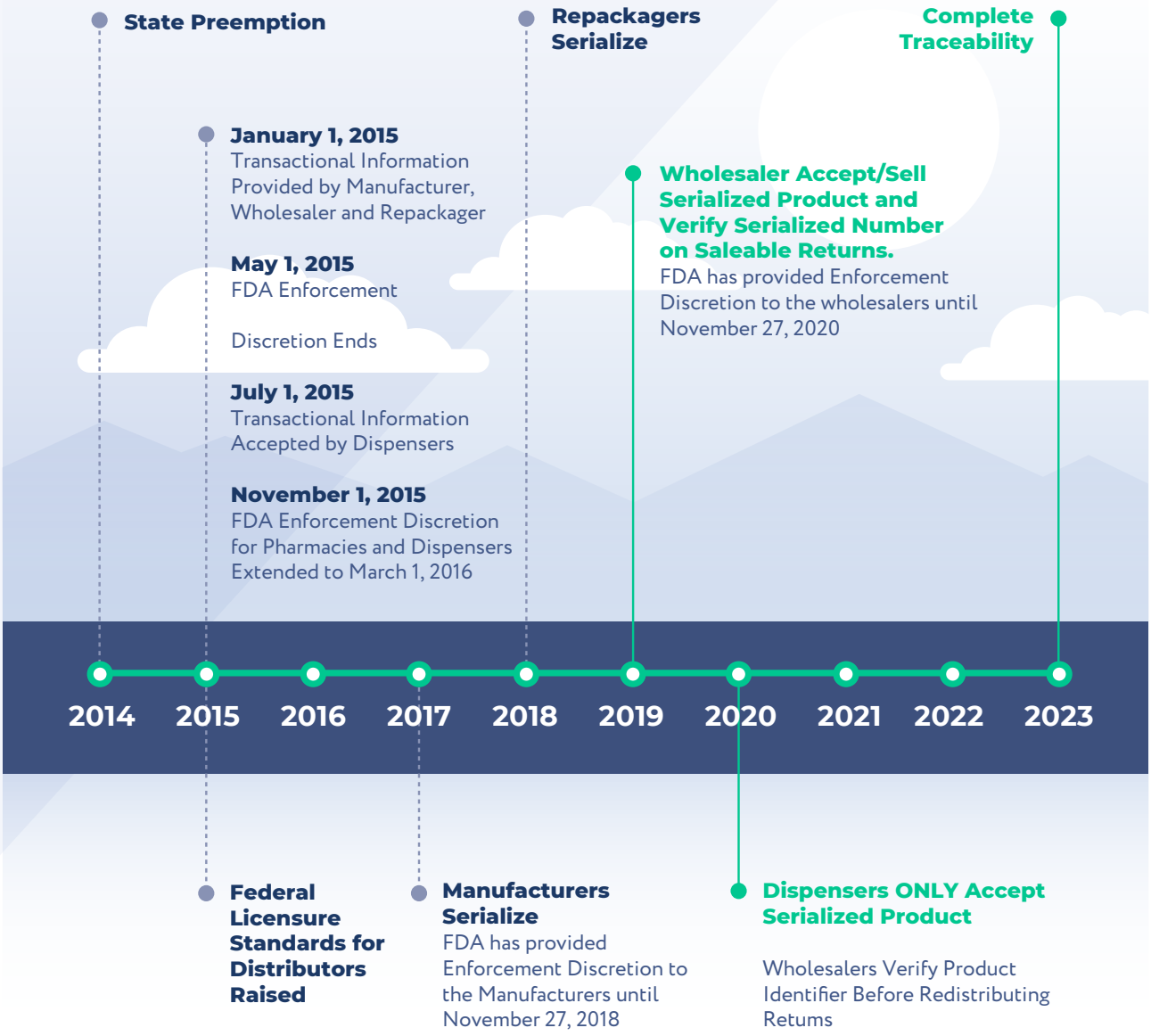
Date of effectiveness: November 27, 2023!

Manufacturers and Distributors have been working compliance for the past several years. If you feel you are a little behind, then 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	Aggregation capabilities set up and tested. Include exceptions, reporting, tracking	Most exceptions occur in handling of overage/underage, unpacking and repacking transactions
3	Work on EPCIS message exchange for various levels of hierarchy	This is arguably the one area where boring, technical expertise is needed
4	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 to tweak processes
5	Test with greater volume and move to production	Testing with greater volume indicates if your solutions and processes are scalable to production-grade data
6	Live in production	No later than end August 2023, to allow at least 2 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 track-and-trace. Over the past 7 years, with more than 100 years' of combined traceability experience in pharma, we find the following capabilities are most sought after by manufacturers and distributors:

- Help with GS1 identifiers
- Communication, i.e. B2b information exchanges including EPCIS
- Integration, especially solution integrations
- Help with master data setup, clean up
- Various regulatory reporting, and understanding of regulations
- Business benefits of serialization
- What others in the industry are doing
- What else is coming, i.e. roadmap, future compliance, other market/region regulations, etc.

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.

3Keys

CONSULTING
PRODUCT DEVELOPMENT
SUPPORT