

Drug Quality & Security

Overview

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Why Drug Quality & Security - Background

- ▶ 4 billion US prescriptions in 2007
- ▶ 1% or 40 million may have been filled with counterfeits
- ▶ California accounts for 10% of prescriptions (4 million)
- ▶ Projected \$75 billion counterfeits worldwide

Few Statistics....

- ▶ FDA counterfeit drug cases:
 - No. in 2004-2007 > 2x of 2000-2003
 - No. in 2003 ~ 5x of 2000
- ▶ In 2007, FDA counterfeit drug cases resulted in 71 arrests, 50 convictions, and \$26.5 million in fines and restitution
- ▶ In April 2008 the FDA had 20 open counterfeiting cases from just one of two regional California offices

Business Drivers

- ▶ Anti-counterfeiting, combat diversion, brand protection, supply chain efficiency
- ▶ Immediate Compliance to US Drug-Supply Chain Safety Act (DSCSA) – Jan 2015
- ▶ Compliance to evolving Global Traceability Regulations

Drug Quality and Security Act (DQSA)

- ▶ Obama signed into law on 11/27/13
- ▶ Title I – Drug Compounding
- ▶ Title II – Drug Supply Chain Security Act (DSCSA)
- ▶ 4 Core areas of DSCSA
 - Product Tracing
 - Serialization
 - Verification
 - Request for Information

4 Core Areas of DSCSA

Product Tracing

- Single document which includes transaction information, transaction statement, and transaction history*
- Provisions for both lot and unit level tracing

Serialization

- Apply a Standardized Numeric Identifier (SNI) to uniquely identify a package or sealed homogeneous case.
- Must not buy or sell unless product is serialized
- Rolling timelines starting November 27th, 2017

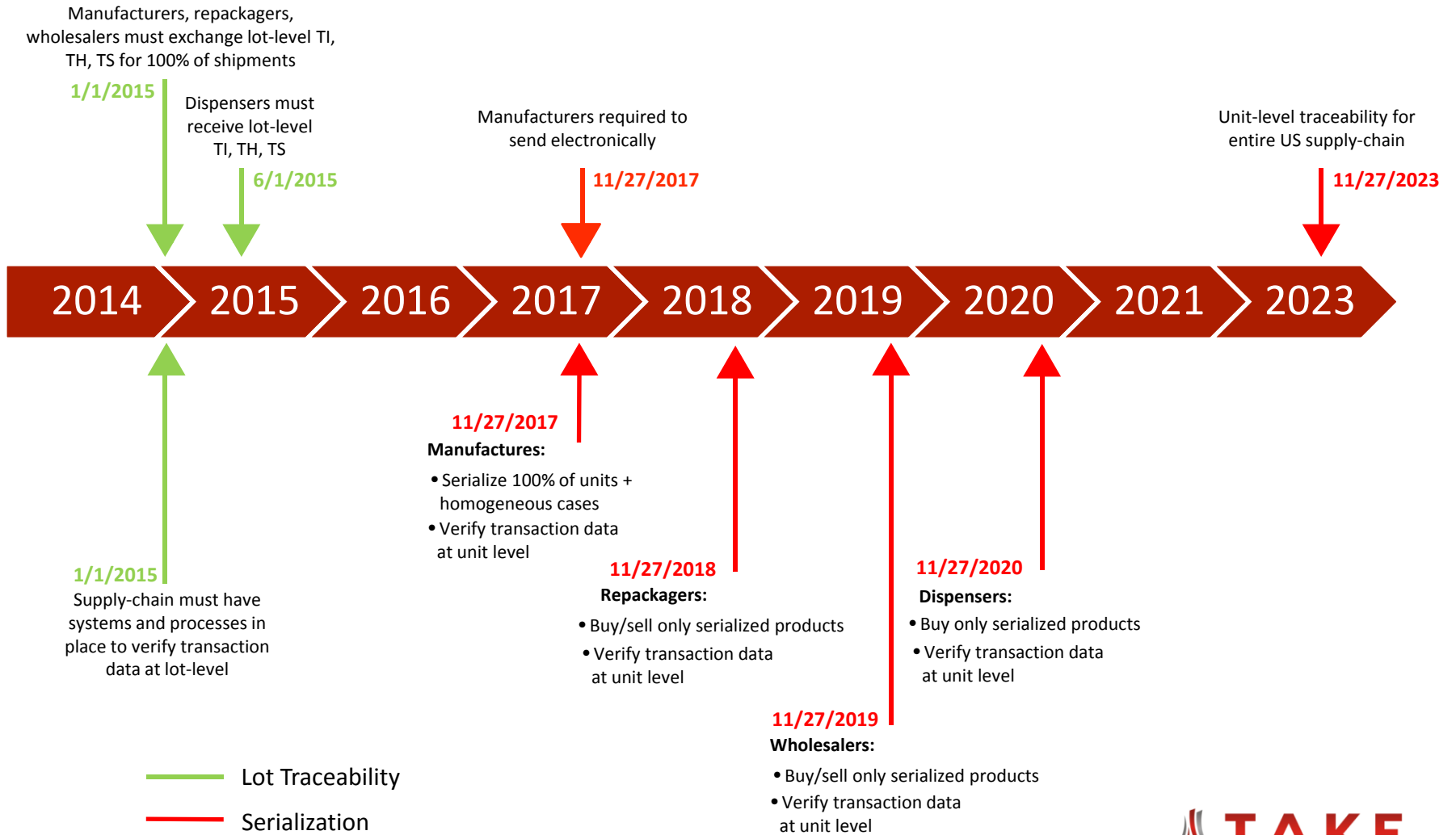
Verification

- Determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date
- Systems and processes to validate TI, TH, TS for product in possession.
- Lot verification starts January 1st, 2015
- Unit-level verification coincides with serialization timelines

Request for Information

- Must respond within 1-2 business days to a request for TI, TH, TS in the event of suspect or illegitimate product
- Must respond within 24 hours to a request for information at a unit level – coincides with serialization timelines

DSCSA Timelines



Definitions

Transaction Information	<ul style="list-style-type: none">• The proprietary or established name or names of the product• The strength and dosage form of the product• The National Drug Code number of the product• The container size• The number of containers• The lot number of the product• The date of the transaction• The date of the shipment, if more than 24 hours after the date of the transaction• The business name and address of the person from whom ownership is being transferred;• The business name and address of the person to whom ownership is being transferred.
Transaction History	A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
Transaction Statement	<p>A statement, in paper or electronic form, that the entity transferring ownership in a transaction—</p> <ul style="list-style-type: none">• Is authorized as required under the DQSA• Received the product from a person that is authorized as required under the DQSA• Received transaction information and a transaction statement from the prior owner of the product• Did not knowingly ship a suspect or illegitimate product• Had systems and processes in place to comply with verification requirements• Did not knowingly provide false transaction information• Did not knowingly alter the transaction history

Key Questions - January 1st, 2015

How can I verify the correct data is available to ship / receive?

How do I create, store, retrieve, and append transaction records?

How do I correlate outbound lots with their transaction histories?

How can I prevent shipping more than received for a specific lot?

How do I provide support for non-EDI capable trading partners?

How will customer service representatives handle exceptions?

Thank you