DSCSA
The Time is Now!

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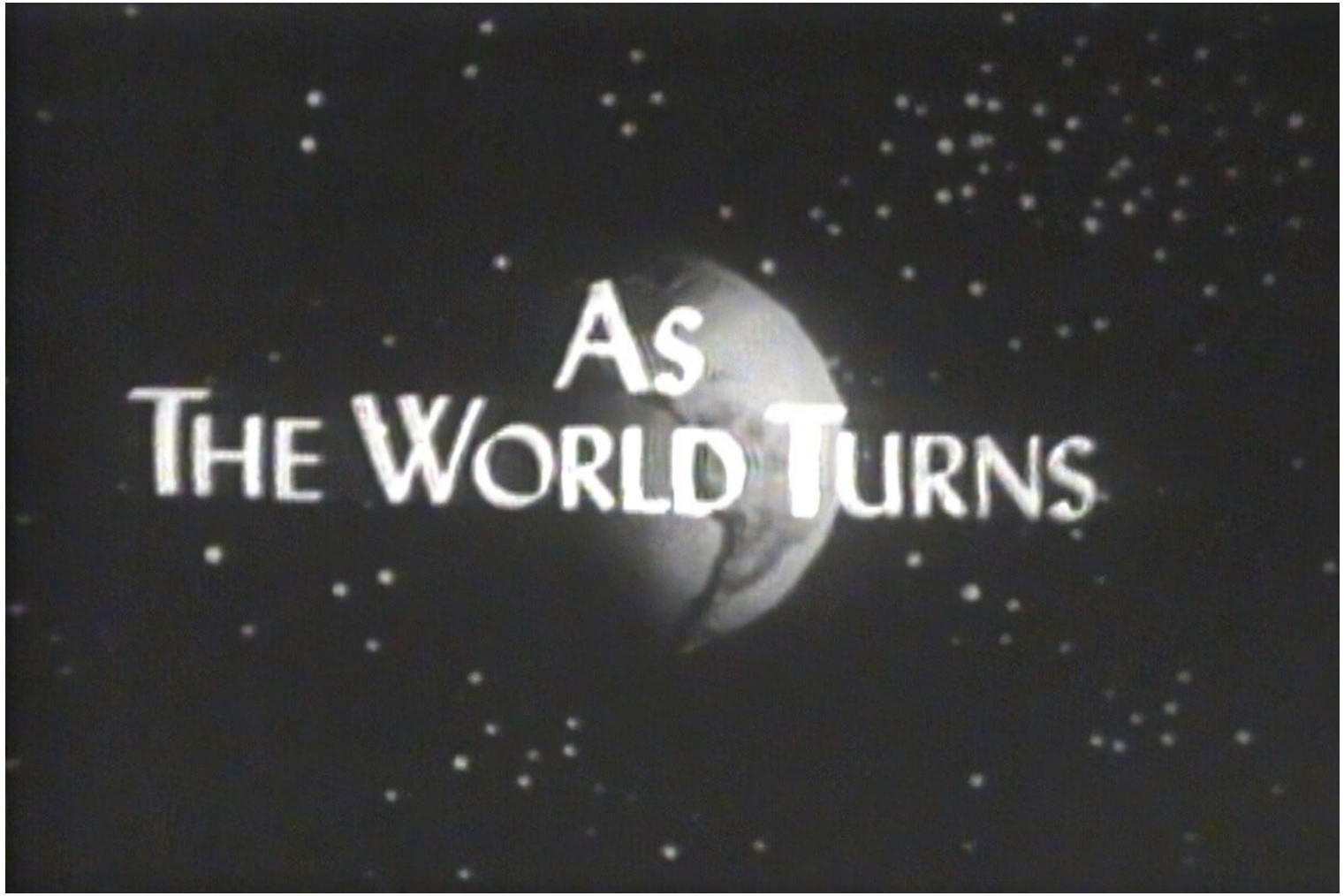
How fast is the earth moving?



A history of my journey

Training

Preparing

- Understanding the law
- Setting goals and timelines
- Networking
- Writing SOPs
- Defining systems, processes, hardware and software requirements
- Defining the internal team

Finding a Service Provider

- RFP process
- Reporting and support needs

Tracking and encouraging participation from upstream trading partners

Why DSCSA?

- Traceability
- Focused on transfer of ownership
- Counterfeit and suspect products
- Recalls
- Unified Federal vs. State Regulations
- Benefits
  - Recalls- lot number tracking
  - Expiration dates tracking and visibility
  - 2D bar codes and EPCIS provide more product data

FDA Established Timeline

The goal for the Drug Supply Chain Security Act

- Interoperable electronic unit-level traceability (serialization) of every regulated drug in the United States
- Key dates of the DSCSA timeline include the following:
  - **November 27, 2013:** DSCSA enacted
  - **November 27, 2014:** Third-party logistics providers (3PLs) must report licensure information to FDA annually
  - **November 27, 2015:** Manufacturers must print lot numbers on packaging
  - **November 27, 2017:** Manufacturers must serialize and verify products
  - **November 27, 2018:** Re-packagers must serialize products
  - **September 23, 2019:** FDA delays enforcement of saleable returns requirement for wholesalers
  - **November 27, 2019:** Wholesalers/distributors can only receive and distribute serialized products
  - **August 25, 2023:** FDA announces extended stabilization period, postponing enforcement for one year
  - **November 27, 2024:** Full interoperable electronic unit-level traceability for all stakeholders

Drug Supply Chain Security Act

Dispenser Requirements

2015 - 2017

- Purchase products from licensed trade partners
- Receive & retain lot traceability (TI, TH, TS) from suppliers
- Provide TI, TH, TS if selling or loaning product
- MAH must send TI, TH, TS in electronic form only (2017)

2020

- Only transact in serialized product (i.e., receive & ship)
- Verify product identifier, including serial and lot number, for suspect product investigation

2023

- Receive and Store serialized TI and TS in an electronic database
- Transaction History (TH) is no longer required
- Fully electronic, interoperable, system
- Unit level traceability
- EPCIS replacing ASN

tracelink.

Drug Supply Chain Security Act

Manufacturers and Distributor Requirements

2015

- Federal licensure standards for Wholesalers
- Transaction Information, History & Statement (T3) for each shipment provided by Manufacturers and Wholesalers

2017 - 2018

- Manufacturers serialized product with 2D barcode[1]
  - GTIN
  - Serial Number
  - Lot Number
  - Expiration Date

2019 - 2020

- Wholesaler can only accept and sell serialized product
- Wholesalers verify product identifier for salable returns
- MAH responds to product identifier verification[2]

2023

- Exchange serialized Transaction Information and Statement
- Product identifier verification for suspect product investigation
- “Product Tracing”
- Authorized Trade Partner credentialing

EXEMPTIONS UNDER DSCSA

- Intracompany distributions
- Distribution of product samples
- Distribution of over-the-counter drugs
- Medical convenience kits
- Anesthetics, Anti-coagulants, Vasopressor, IV solutions, Sympathomimetics
- Approved animal drugs
- Medical gas distribution
- Blood and blood components for transfusion

Implementation Time

Upstream

- Suppliers
- Wholesalers

Downstream

- Dispensers

Finding resources

- HDA
- NACDS
- PDG
- FDA

What do you need for your Pharmacy in November ’24?

Have a system to receive and transmit transaction information as product changes ownership

24-hour time limit for notification to trading partners of Illegitimate product

GLNs-unique identifiers that define the parties in the change of ownership (Transaction)

Purchased from GS1

Assigned by location

Considerations unique to your business

- Number of direct suppliers vs. wholesale only model
- Store vs. warehouse receiving
- Training and SOPs
- Data flow
  - Receive and set up EPCIS internally vs. using a third-party provider
- Service provider selection and management
- Who will enforce and audit?
  - State boards
  - FDA

Caution

"If a wholesale distributor, dispenser, or re-packager purchases product and identifies a potential clerical error or other discrepancy in the product tracing information it received, that trading partner should resolve the error or discrepancy within 10 business days."

Carefully inspect when receiving	• Broken seals • Altered tape or wrap
Handle clerical errors	• Trading partners should work together to resolve • No further distribution of the product • Document

"If either trading partner determines the product is suspect or illegitimate, the trading partners must follow applicable verification requirements, including quarantine, investigation, and proper disposition."

DELAYS and Surprises

- Enforcement discretion
- Stabilization period now until 11/27/24
- Lack of an “interoperable system”
- 2D bar code reader shortages
- Cloud server connections
- Aggregation issues at manufacturers
- Each vs. Case invoicing issues
- What to do with EDI
- 10 days to clear a suspect product
- Space for the 2D bar code on the bottle

What do you do?

KEEP MOVING FORWARD!

THE WORLD WILL KEEP TURNING

SOPS

TRAINING

ENCOURAGE SUPPLIERS AND WHOLESALERS WHO ARE UPSTREAM