IMPLEMENTING FSMA 204 – LESSONS LEARNED FROM THE DSCSA
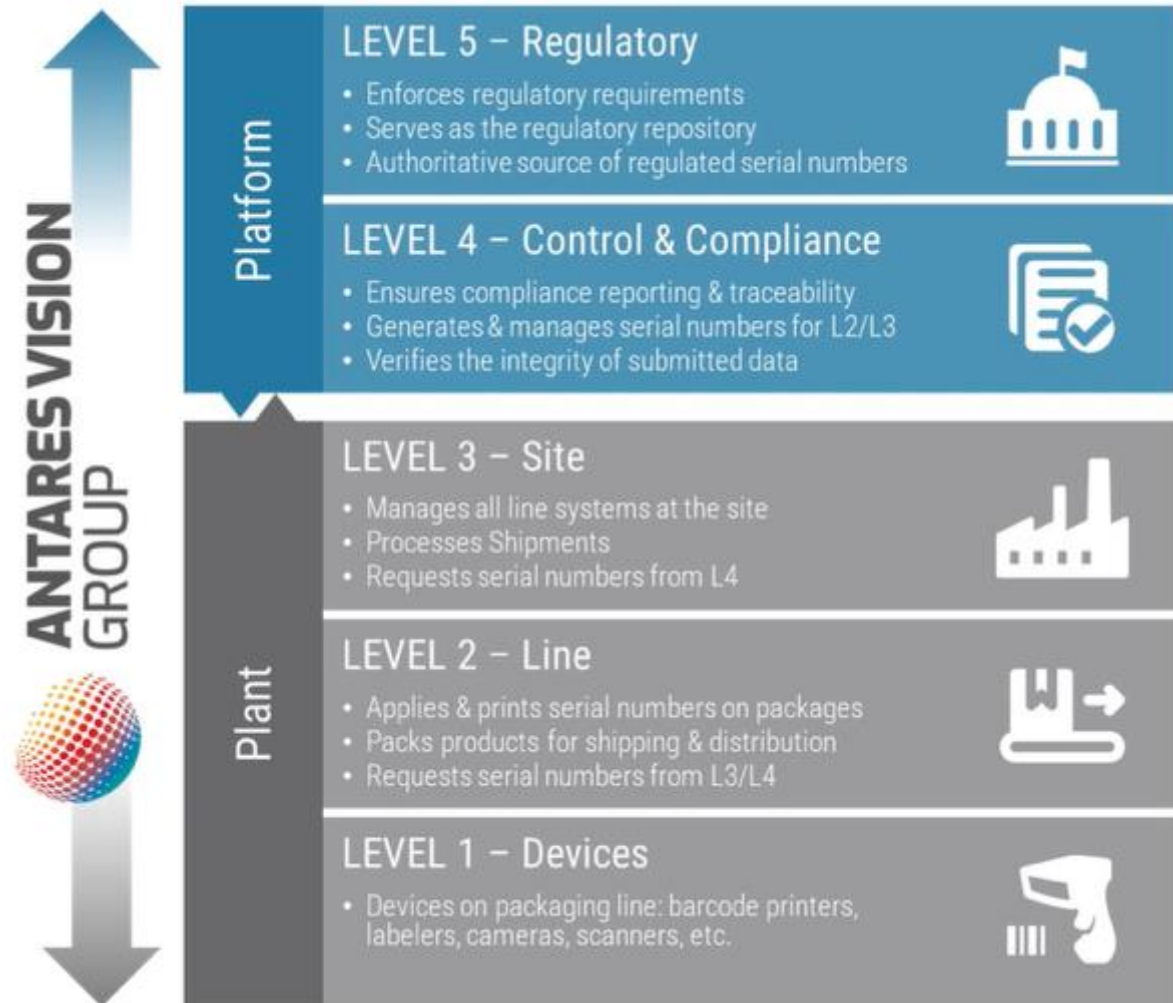
Who we are

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LEVEL 5 – Regulatory
- Enforces regulatory requirements
- Serves as the regulatory repository
- Authoritative source of regulated serial numbers

LEVEL 4 – Control & Compliance
- Ensures compliance reporting & traceability
- Generates & manages serial numbers for L2/L3
- Verifies the integrity of submitted data

LEVEL 3 – Site
- Manages all line systems at the site
- Processes Shipments
- Requests serial numbers from L4

LEVEL 2 – Line
- Applies & prints serial numbers on packages
- Packs products for shipping & distribution
- Requests serial numbers from L3/L4

LEVEL 1 – Devices
- Devices on packaging line: barcode printers, labelers, cameras, scanners, etc.

WHAT IS DSCSA

DSCSA - DRUG SUPPLY CHAIN SECURITY ACT

Industry Focus: The DSCSA primarily targets the pharmaceutical industry.

Purpose: It aims to ensure the safety and security of the pharmaceutical supply chain by establishing requirements for tracing prescription drugs as they move through the supply chain, from manufacturer to dispenser.

Key Provisions: The DSCSA mandates the implementation of systems for product tracing, verification, and detection of suspect products. It requires pharmaceutical manufacturers, repackagers, wholesale distributors, and dispensers to exchange product and shipping information at the lowest unit of sale via serialization of each sellable unit and aggregating that serialized information based on how it is shipped.

Timeline: The implementation of the DSCSA has been in progress for the last 10 years, with full compliance expected by 2024.

CHALLENGES ALONG THE WAY

MAJOR CHALLENGES DURING THE IMPLEMENTATION OF DSCSA

1. EQUIPMENT

- Every line that packaged pharmaceutical products had to have serialization capability added

- Additional equipment was required for the verification of serialization data.

2. PROCESS

- All SOPs that dealt with the movement of product throughout the manufacturing and distribution process needed to be adjusted to accommodate for tracking the additional data required to comply with the DSCSA

- Inspection and Rework activities needed to be adjusted due to the requirements of keeping the aggregation of data correct at the shipper and pallet level

3. SYSTEMS

- Many manufacturers and distributers underestimated the effort required for the data collection activities needed to support the capture and sharing of serialized data.

- In many cases, existing system were not designed to support the additional process/data required to support the regulation

4. COMMUNICATION

- Various "maturity" levels of technology capability of the partners
- Understanding of the standards required for successful transmission of the required data.

FSMA 204 OVERVIEW

What will the Food Traceability Rule require?

The rule requires covered persons to maintain records for foods on the Food Traceability List (FTL) to support more efficient and accurate traceability of potentially contaminated food

What will the Food Traceability Rule require?

- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
- Covers the entire food supply chain
- Includes both foreign and domestic entities
- Full and partial exemptions may apply

- Where are you going to store the data and events that must be captured and maintained?
  - Systems, Process.
- How will you create the receiving and shipping events, and have you talked with your partners?
  - Communication, data sharing.

Image: FDA.gov

Thank you!