Johnson & Johnson SUPPLY CHAIN

Johnson & Johnson Supply Chain's Experience: Implementing DSCSA's Product Identification Requirements

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Agenda

- Practical lessons learned
  - Serialization
  - Customer track & trace pilots
- Challenges encountered
- Solutions implemented

Johnson & Johnson

Global Presence

- Global leader in Health Care
- More than 275 operating companies in 60 countries
- Selling products in more than 175 countries
- Approximately 128,000 employees worldwide

Johnson & Johnson Aspiration

Caring for the world, one person at a time, inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Johnson & Johnson Credo

COMMON SET OF VALUES UNIFYING DIVERSE BUSINESS

- Created in 1943
- Drives deep commitment to ethical principles
- The Four Tenets
  - Customers
  - Employees
  - Communities
  - Stockholders

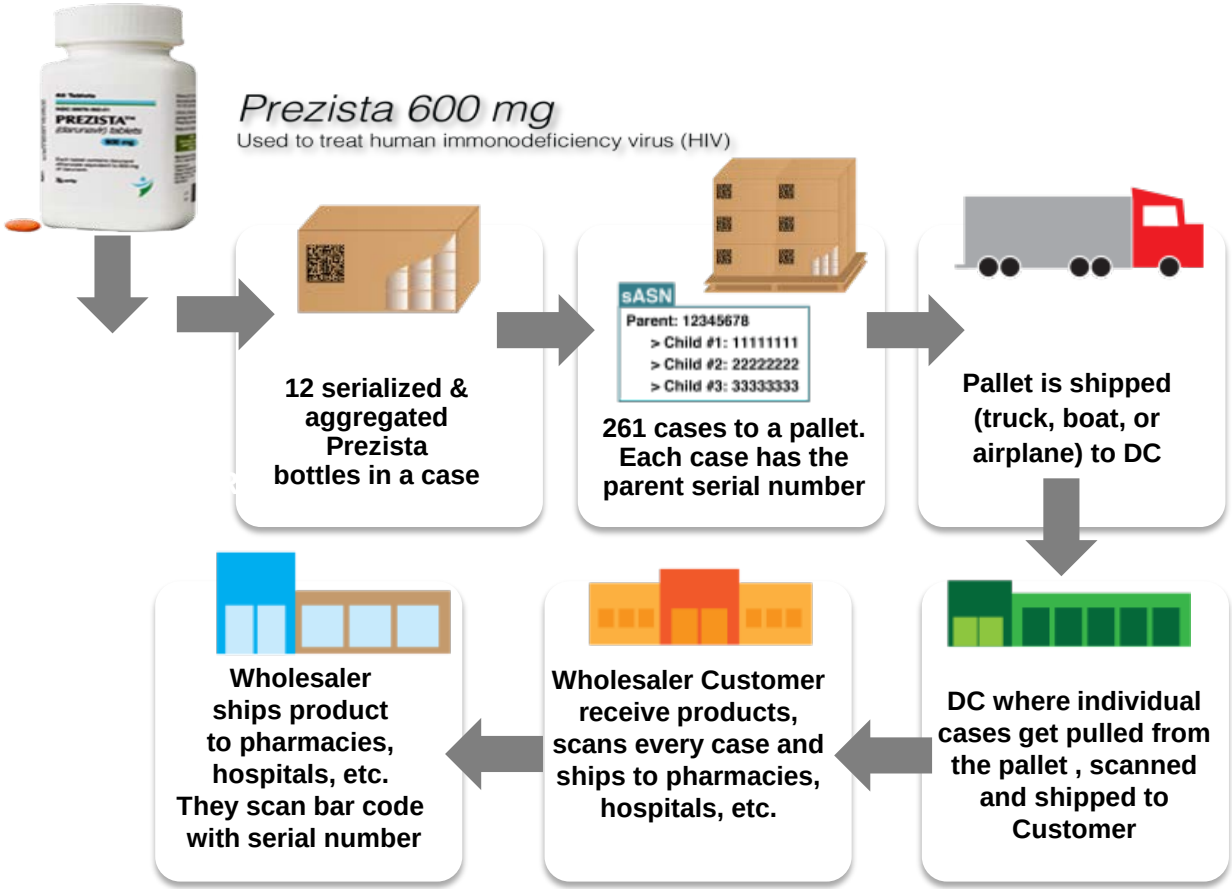
DSCSA product identification requirements

Item level serialization using FDA's Serial Number Identifier guidance

A **unique identification number** is assigned to **each item** identifying it with a product number and associated serial number. It's applied at every package level (bottle, case, and pallet).

DSCSA unit level tracing

Preparing for the next phase



Regulatory mandates are demanding visibility of products from point of packaging to point of dispense.

- These mandates demand improved supply chain visibility
- Products are identified, serialized, authenticated, tracked & traced
- What product? Where has it been? Where is it going? How long has it been there?
- Using data captured as product moves through the supply chain, answers questions as to the disposition of inventory

Practical lessons learned

Serialization, aggregation and verification

- Program on-track / on-budget for compliance with no supply interruption
- Highly-complex, end-to-end program
- Numerous internal and external dependencies
- Critical to proactively manage vendor performance

Practical lessons learned

Numerous internal and external dependencies required

- Align on FDA guidance
- Conformance to GS1 standards
- Adopt HDA/industry guideline – e.g., case label
- Internal program standards, systems and processes
- Integration into production planning

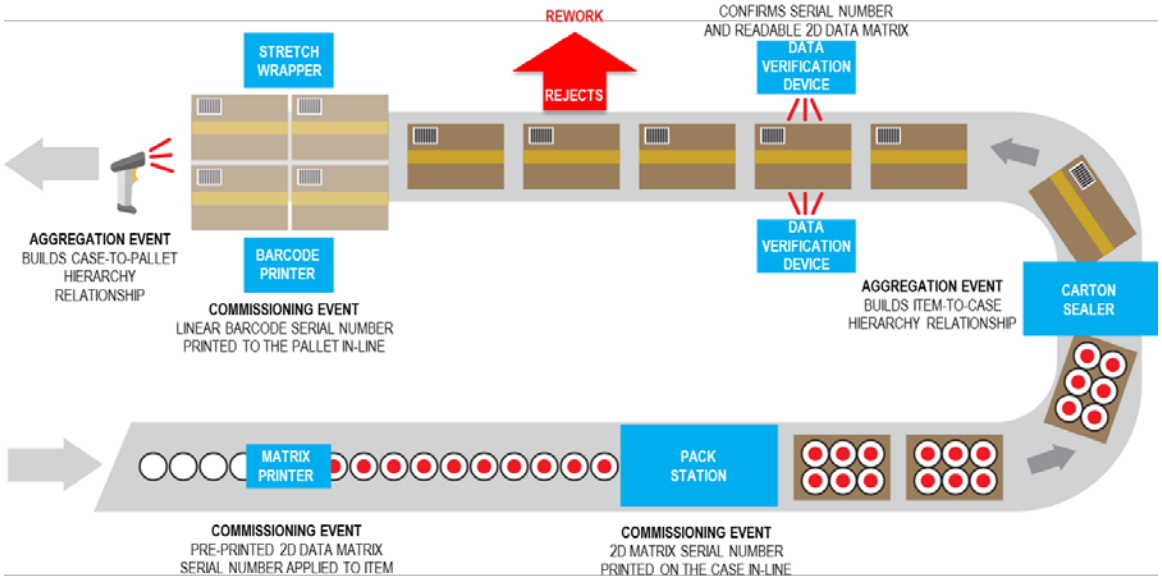
Practical lessons learned

Manufacturing benefits realized through standards, process improvements and information

- Reduction of manual work, increase in productivity
- More precise data available for investigations of deviations or complaints
- Increased efficiency in product issue resolution
- Improvements in label print quality
- Reduction in amount of disposable materials and waste

Practical lessons learned

Distribution center operations

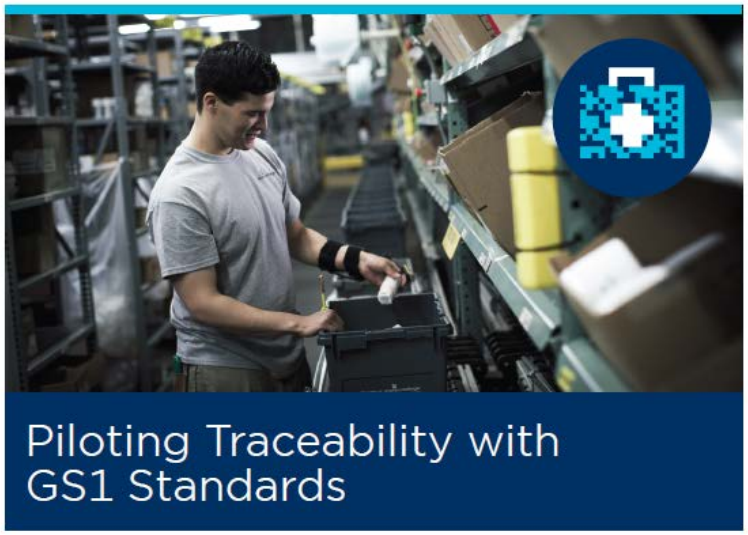


- **NO** additional headcount was necessary
- Savings from better accuracy and standardized labelling for error correction
- Higher fidelity inventory accuracy and visibility
  - Reduced need for checks and counts
  - Reduction in claims and credits

Practical lessons learned

Customer track & trace pilots

CASE STUDY



Piloting Traceability with GS1 Standards

AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings

CHALLENGE

The Federal Drug Administration (FDA) regulation requires that the pharmaceutical industry implement end-to-end traceability by 2023. Trading partners throughout the supply chain must implement and test GS1 Standards-based solutions in real-world pilots to meet the deadline for interoperability.

SOLUTION

- Collaboration is critical
  - 1:1 pilots
  - HDA pilot
- Enabled through standards
- Clear interpretation of standards
  - E.g., expiry date, unit of measure
- Process alignment
  - E.g., data must arrive before physical product
- Potential need for verification and master data service
- Opportunities for value creation

Challenges encountered

- Serialization adds extra layer of complexity
- Aggregation adds ~50% to line retrofitting cost and implementation time
- Lower productivity initially – e.g., headcount increase on manual operations
- Protecting impact to overall equipment effectiveness (OEE)
- Print quality (e.g., white vs. black box for laser printing)
- Alignment with external manufacturers – serialization vs. track & trace
- Difficulty standardizing globally

Solutions implemented

Critical components to manage risk and drive consistency

- Multi-tiered governance structure with global program management office
- Process review and internal standards, systems and technology
- End-to-end view
- Vendor management program
- Serialization training centers
- Change management program
- Customer collaboration pilots

7 Billion Reasons to Care

Serialization and track & trace will benefit patients and consumers around the globe