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

• 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