

DSCSA Serialized Product Management in Warehouse and Logistics Operations

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Objectives

- Impact of serialization on warehouse operations
- Business and operational requirements
- Serialized product operations from container management, pick / pack, ship, verification
- Tools to manage serialized processes



How Compliance Data is Transmitted

DSCSA 2015

- ASNs / EDI 856 have long been used for order management
- Beginning in 2015 (DSCSA Phase 1), our industry began including T3 data on the ASN:
 - Transaction Information
 - Transaction Statement
 - Transaction History
 - All at the lot level
- In today's world, if you receive an ASN, it's fairly safe to assume that you've also received T3 data for compliance
- Are you validating the receipt of T3 data at all today?

DSCSA (now)

- The ASN will no longer be used to transmit compliance information
 - The ASN will remain in use for logistics purposes
- Data Exchange using EPCIS is the industry's accepted format to transmit the new T2 data:
 - Transaction Information
 - Transaction Statement
 - Serialized data at the item level
- How do you want to validate the receipt of EPCIS serialized compliance data?

Serialization Business Requirements



Serialization and traceability creates the need to track each unit throughout the production, warehousing and distribution processes



Aggregation is needed rather than scanning each item



Warehouse environments require a mobile experience for ease of use and convenience













Events and actions that must be tracked

- Container Aggregation, Disaggregation, Reaggregation
- Serial Number Status changes at the container or item
- Changes in Custody or Ownership – Ship, Receiving, Return, Recalls
- Verification needs



Challenges for ERP/WMS to Become “Serialization Aware”

| Challenge | Business Impact / Pain Point | TraceLink | ERP/WMS |
|---|---|---|---|
| Domain Expertise | Serialization, GS1, EPCIS, DSCSA, EU FMD, etc. – these are not germane to most ERP/WMS Vendors. There is no reason for ERP / WMS / PMS vendors to maintain staff and knowledge and therefore it is challenging for them to deliver solutions |  |  |
| Invasive Change | The fundamental model of ERP / WMS does not support serialization through GS1 and EPCIS. It will be very difficult and impractical to perform many of these functions. Why duplicate the data that is already resident in TraceLink |  |  |
| Scalability Concerns | The data volumes and processing requirements have increased 10x with serialization. Previously needed to know that I am shipping 100, now I need to know EXACTLY which 100 I am shipping. |  |  |
| Integration with Serialization SOR | Any serialized transactions, especially those related to the product hierarchy, aggregation and inference need to immediately synced with the serialization system of record (SOR). This will require that the ERP/WMS design, deploy and maintain a product hierarchy integration with TraceLink |  |  |
| Continuous Compliance | Serialization and compliance is a decades long journey that will continue to evolve and improve to provide the benefits of product visibility and patient safety. ERP/WMS Vendors are not prepared for this evolution of changes |  |  |

Serialized product operations readiness

- The Big 3 wholesale distributors have set dates for their suppliers outlining their expectations for serialization and serialized product data exchange.
- Are you to sending aggregated EPCIS data to your customers; are you receiving aggregated EPCIS data from your suppliers.
- What scanning processes and technologies are you using or exploring to support serialized rework, shipping, pick/pack/ship, receiving, verification ?
- Receiving strategy
 - Receive at aggregated level and/or below container level
 - Inference and implicit receiving
 - Spot check

Post Packaging Container Management



- Ensure that aggregation hierarchies remain valid
- Update serial number status for product that has been damaged or destroyed while in storage
- Update aggregation and serial number status to accommodate sampling procedures
- Support for container re-labeling and label replacement for damage labels

Packing & Shipping



- Incorporate the shipping of serialized product into standard shipping processes
- Integrating serialization into picking and packing process
- Verify correct product / lot / quantity / serial numbers shipped and update the WMS/ERP and your serialization repository
- Ensure WMS/ERP and Serialized operations remain in-sync

Receiving



- Incorporate serialized product into standard receiving processes
- Verify correct product / lot / quantity / serial numbers received and update both WMS/ERP and your serialization repository
- Ensure WMS/ERP and Serialized Operations remain in-sync
- Leverage aggregation so only top level container serial numbers need to be scanned

Verification



- Verify serialized product for returns
- Setup processes to verify the authenticity of suspect / illegitimate product
- Setup procedures like quarantine for error handling and for returning serialized product back to inventory

Smart Inventory Tracker - TraceLink Mobile App



Native TraceLink Mobile Application

- Scan and capture product at the each, case/pack, and pallet levels
- Purpose built database architecture designed for high volume
- On demand scalability through native cloud architecture and services
- Operates alongside ERP and WMS and integrates with these
- Runs on wide variety of commercially available mobile devices
- Supports all distribution processes (receiving, returns, pack, ship, rework, container management, verification, status updates)

Key Takeaways

Managing and maintaining serialized inventory is a necessity

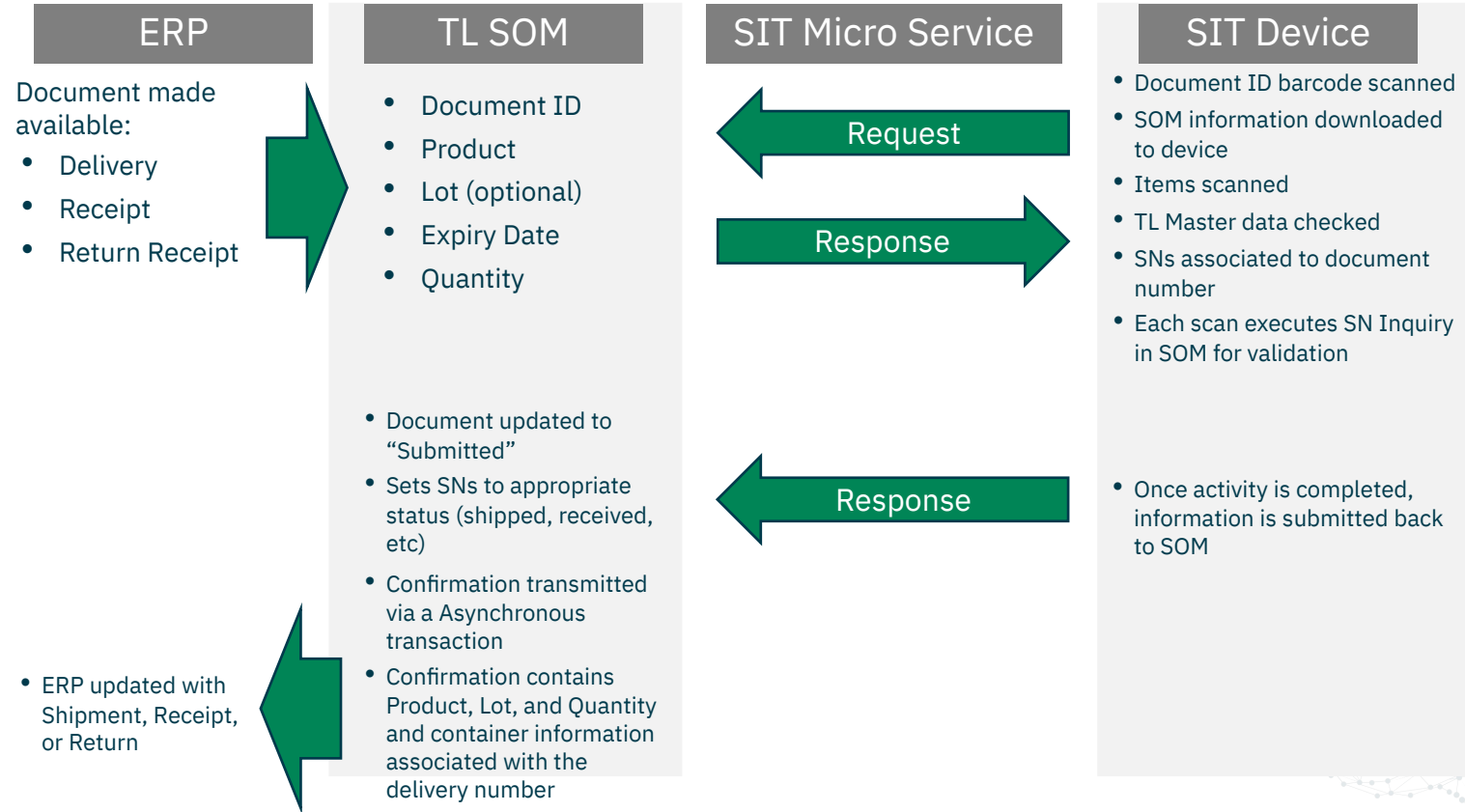
- ✓ Identify processes impacted
- ✓ Implement a Serialization System of Record
- ✓ Integrate with existing enterprise systems
- ✓ Formulate SOPs for serialized operations & error handling

Visit the Product & solution demo fair for demos of the SIT application

Thank You



Integrated ERP Data Flows



Smart Inventory Tracker

Mobile data capture that extends Serialization and Traceability to the edge of the supply chain

Native TraceLink Mobile Application

- Scan and capture product at the each, case/pack, and pallet levels
- Manages all the data exchange with other TraceLink applications
- Optional integration to local warehouse systems
- Can be used globally for any serialized product

Enable Serialized Process Orchestration

- Mobility allows access at points where physical product is stored
- Runs on wide variety of approved commercially available devices
- Supports all distribution processes (receiving, returns, pack, ship, rework, container management, verification)

