

Orchestrating End-to-End EPCIS Data Exchange for Serialized Products

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Learning Objectives

- DSCSA EPCIS Orchestration: Is it more than just sending a file?
- DSCSA will introduce unprecedented operational processing requirements
- Business use of EPCIS will evolve, which will lead to new requirements and updated integrations
- Data exchange will introduce a new set of exceptions that must be quickly resolved to keep avoid product stockouts

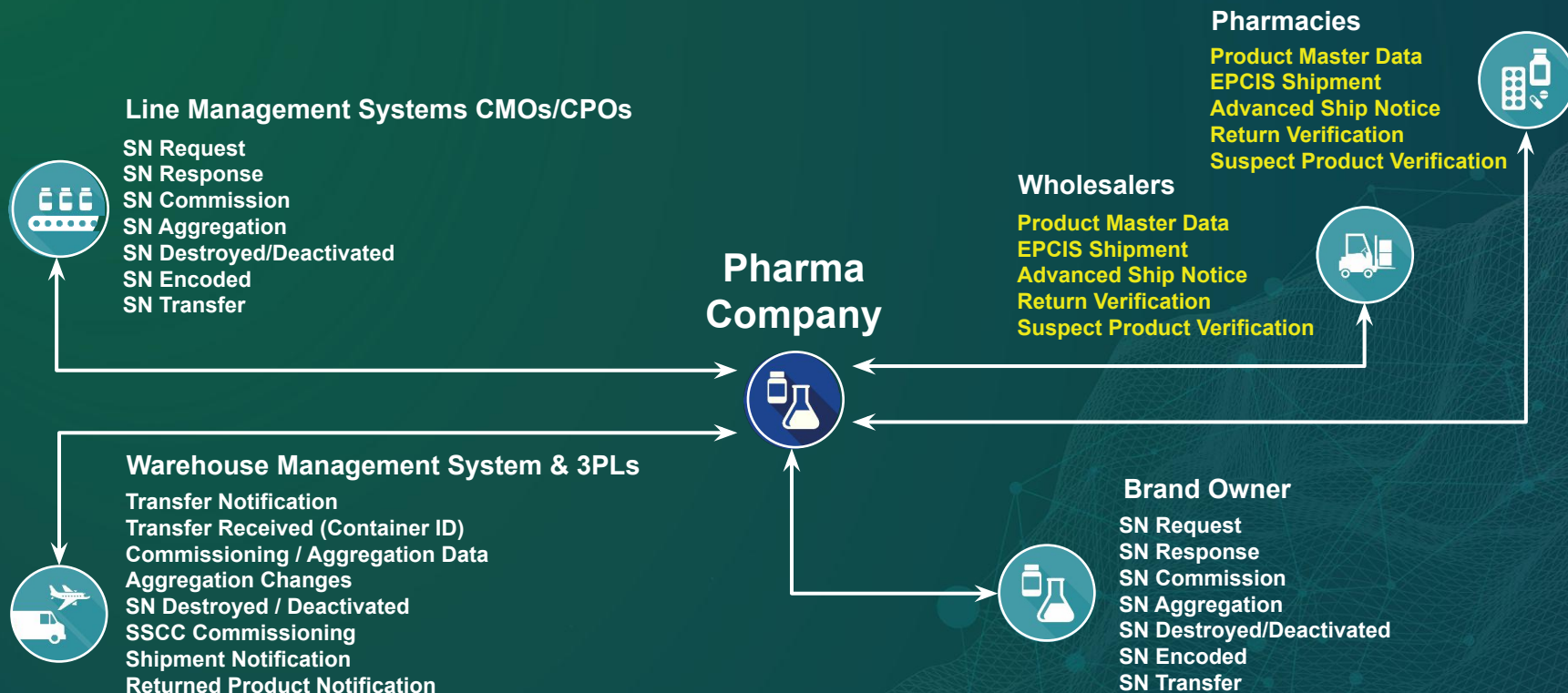


What is involved in the DSCSA EPCIS Orchestration?

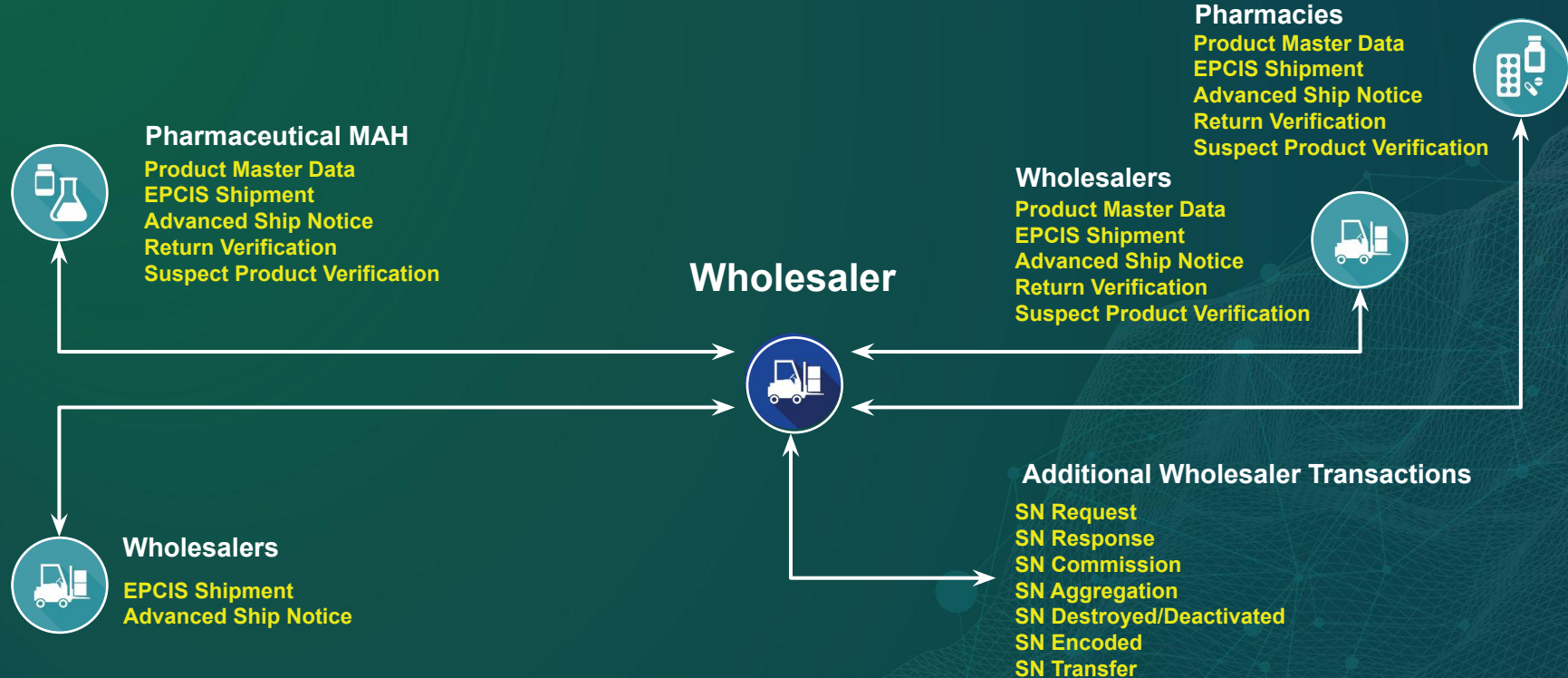
- Serial number creation and inventory management by product
- Serial number allocation to Line Management Systems and CMOs
- Serial number commissioning and aggregation
- Transfer serialized shipment to distribution center or 3PL
- Pick, pack and ship serialized items to a customer
 - Standard shipments
 - Drop shipments
 - Void shipments
 - Receive returned shipment
 - 340B shipments
- Manage serialized shipment exceptions
- Use DSCSA EPCIS data to improve other critical processes such as recalls

DSCSA EPCIS Orchestration

A Pharmaceutical MAH Perspective

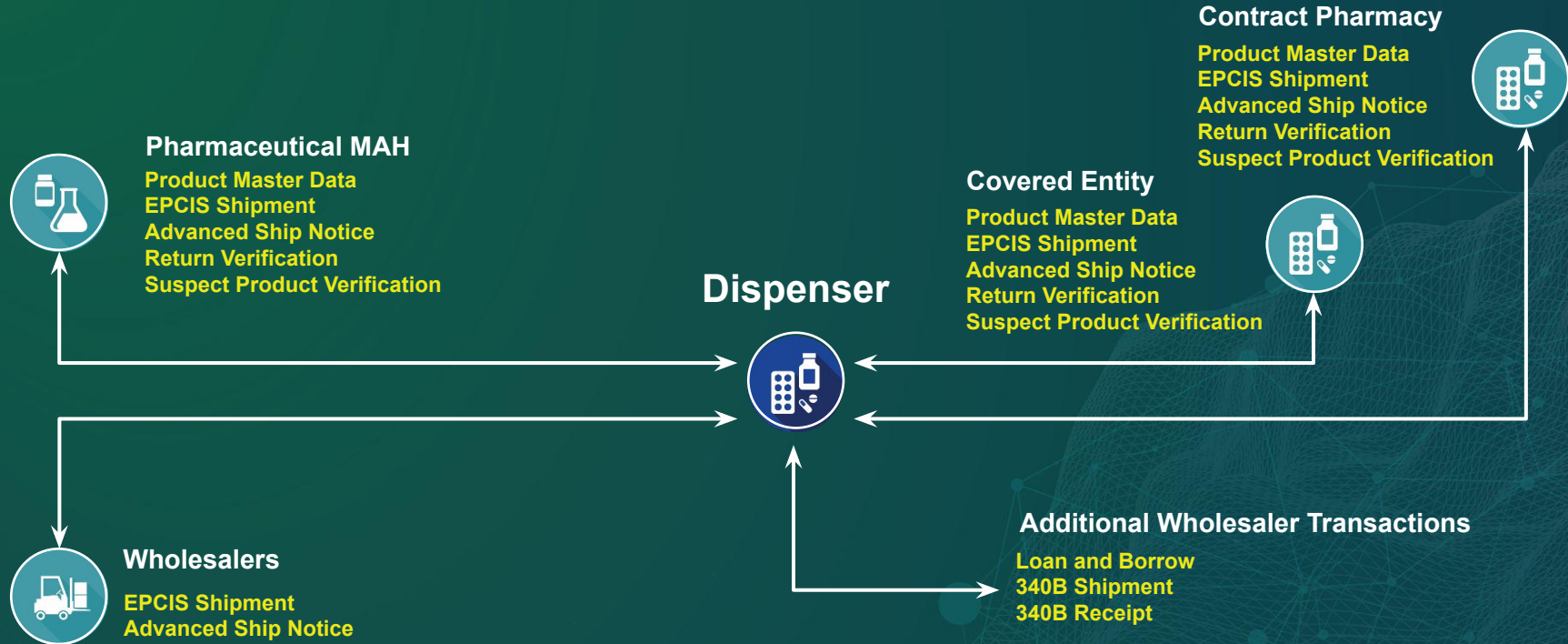


DSCSA EPCIS Orchestration A Wholesaler Perspective



DSCSA EPCIS Orchestration

A Dispenser Perspective



Massive amounts of data must be processed in operational real-time to keep product moving.



Take One
Step

LOT LEVEL TRACEABILITY

1 Transaction to Create a Batch

+

1 Transaction to Pick a Pallet

+

1 Transaction to Ship/Receive a Pallet

+

1 Transaction to Send/Receive an ASN

=

4 Transactions

2 KB of DBMS Storage

ITEM LEVEL TRACEABILITY

10,000 Transactions to Provision Serial Numbers

+

10,000 Transactions to Commission Serialized Product

+

10,000 Transactions to Aggregate Serialized Product

+

10,000 Transactions to Pick Serialized Product

+

10,000 Transactions to Ship/Receive Serialized Product

+

10,000 Transactions to Send/Receive Serialized Product Information

=

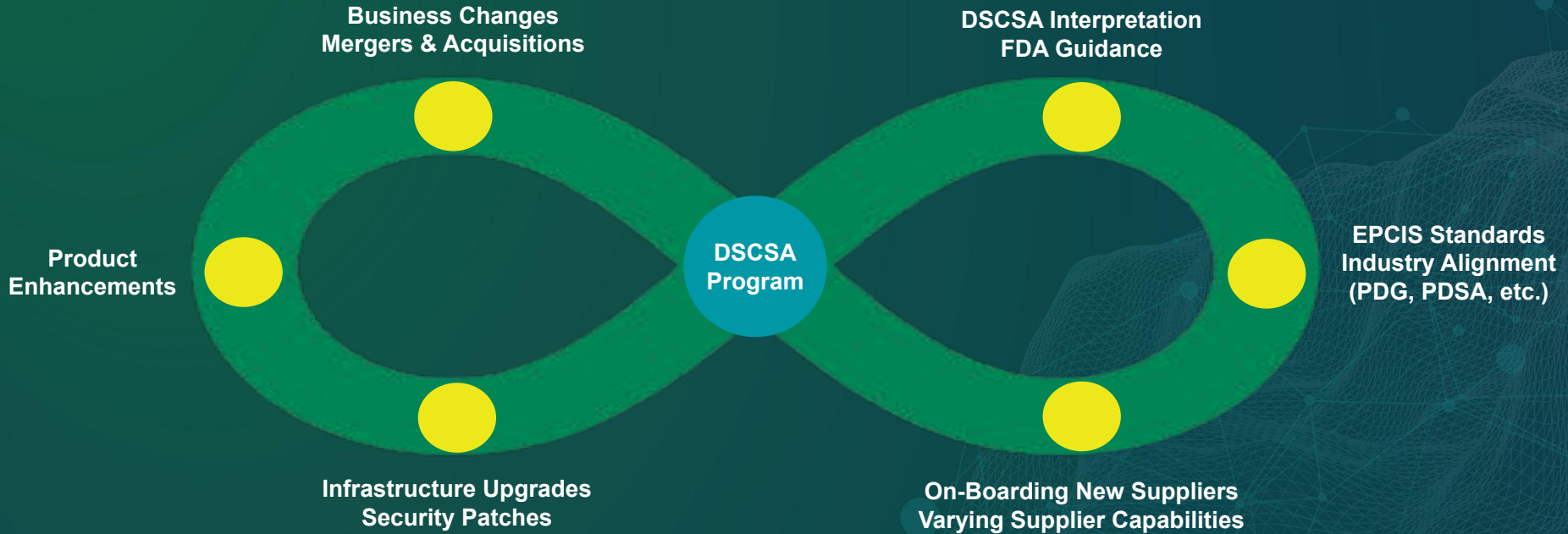
60,000 Transactions

11 MB of DBMS Storage



Climb A
Mountain

DSCSA EPCIS Orchestration requirements will continue to evolve as the industry operationalizes DSCSA.



DSCSA Orchestration will lead to new supply chain exceptions that must be reconciled without delay.



HDA identified 24 total exception types they expect to occur



Email approaches to exception resolution will not scale



Resolution requires collaboration between the pharmacy and wholesaler



Internal issue management and supplier quality systems will not scale



Industry estimates that 1% of shipped products will require exception resolution



Exceptions may occur with the wholesaler or the MAH



Email-based approaches are not scalable nor provide adequate record keeping

DSCSA Compliance Exceptions: Orchestrating Exception Management from Issue Identification to Resolution

Today at 1:30 PM

Key Takeaways

- Final phase of DSCSA requires an orchestration across systems and partners
- Item Level Traceability and DSCSA EPCIS will create unprecedented processing requirements
- Operationalizing DSCSA will lead to new requirements and functionality
- DSCSA will create a need for orchestrated exception management

300+

MAHs, WSDs, Health Systems and Pharmacies Live with DSCSA EPCIS

6,000+

Live integrations for DSCSA EPCIS across the network

5M+

DSCSA EPCIS transactions exchanged in production

A hand is shown from the bottom, holding a glowing, wireframe globe of the Earth. The globe is surrounded by a complex network of white lines and dots, representing a global network or data flow. The background is a blurred cityscape. The text "Thank You." is centered over the globe in a bold, dark blue font.

Thank You.