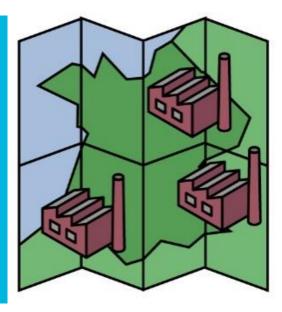


The Global Language of Business

Global standards for wholesalers/distributors – implementation and benefits

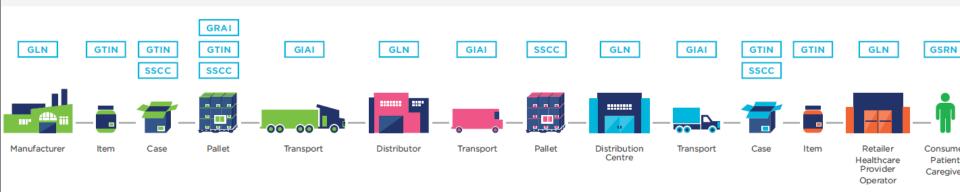


18 April 2016 in Dubai



Identify: GS1 Standards for Identification

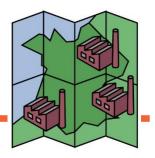
GLN Global Location Number GTIN Global Trade Item Number SSCC Serial Shipping Container Code GRAI Global Returnable Asset Identifier GIAI Global Individual Asset Identifier GSRN Global Service Relation Number



Capture: GS1 Standards for Barcodes & EPC/RFID



EPCIS enables supply chain visibility



• Tracking

Where are the pharmaceuticals I shipped?

• Tracing

Where did this batch of pharmaceuticals come from?

- Chain of Custody (CoC) / Chain of Ownership (CoO) Which parties had custody of these pharmaceuticals?
- Recall

Where were meds produced on 14 April shipped to?

• Asset Management Where are all of the hospital's balloon pumps?



Batch/Lot vs. Serialized Visibility



Feature	GTIN	GTIN + Lot	GTIN + Serial
Low Precision Identification	\checkmark		
Medium Precision Identification		\checkmark	
High Precision Identification			\checkmark
Additional data needs to be physically marked		\checkmark	\checkmark
Serialization required			\checkmark
Traceable item exist in multiple locations at the same time	\checkmark	\checkmark	
Traceable item exist only at one locations at the same time			\checkmark
Product Recall	All units of a given GTIN	All units of a given GTIN + Lot	Only specific units with matching GTIN + Serial
Enables anti counterfeit measures			\checkmark
Enables to monitor products with finite shelf life		\checkmark	\checkmark

DSCSA – 2015, 2017, 2023 Drug Supply Chain Security Act



Packaging level: Saleable units and homogeneous cases

- Data carrier: 2D DataMatrix
- Data elements: NTIN, expiry date, lot/batch, serial number

Deadlines

- 2015: Lot based (March 2016 for dispensers)
- 2017: Serialization by manufacturers and repackagers
- 2023: Full traceability back to manufacturer or repackager

EPCIS is explicitly mentioned in a Nov 2014 US FDA draft guidance as a means for the interoperable exchange of pharmaceutical traceability data



Clearing up misconceptions on EPCIS

EPCIS <u>is</u> . . .

- a complex technical standard in GS1's "Share" layer
- an open ISO standard
- an enabler for commercial traceability solutions & services
- data-carrier-neutral, suited to GS1 DataMatrix barcodes

EPCIS is <u>not</u> . . .

- a product or service for sale by GS1
- an out-of the box solution
- a standalone answer to visibility issues
- GS1's portfolio is greater than the sum of individual parts
- Serialisation and event-based traceability will fundamentally change how a supply chain works... EPCIS will support this





Craig Alan Repec

Senior Manager, EPCglobal Technology

GS1 AISBL Blue Tower, Avenue Louise 326, bte 10 1050 Brussels Belgium +32 2 788 7816

E craig.alan.repec@gs1.org





The Global Language of Business

Global standards for wholesalers/distributors

A DHL Perspective on Serialization Solutions & their implementation

Mike Meakin, Vice President, Global Quality Regulatory & Compliance, Life Sciences & Healthcare, DHL Supply Chain Dubai, April 18th, 2016



Agenda



- DHL GS1 Relationship
- Listening to Customer Needs: Serialization
- Serialization Solutions
- Deep Dive: Serialization Operations in Turkey
- Learning & Recommendations









Long standing collaboration between GS1 and DHL

DHL Supply Chain

Life Sciences & Healthcare Sector:

- 160 GxP facilities worldwide
- 21 GMP facilities worldwide
- 150 DHL Pharmacists
- 44 Countries
- Sub Sectors
 - Biologics
 - Medical Devices
 - Pharmaceuticals
 - Hospitals

	How	we	wor	k
▼	toget	ther	•	

- 10+ years with GS1 Healthcare Sector Voting Member
- CEO John Gilbert on GS1 Board
- CEO NHS SC Nick Gerrard on UK Board
- CEO DGF APAC Kelvin Leung on GS1 HK Board
- Member of Transport & Logistics Sector
- Using GS1 standards in our Supply Chains

GS1

- 111 member organisations
- Member driven
- 150 countries served
- 20 different domains
- 2,500 people helping us
- Over 6 billion transactions a day
- 36 HUG Countries





Listening to Customer Needs: Serialization



A survey among pharmaceutical manufacturers revealed serialization requirements

•

Participant Profile

- 80% work for a big pharma manufacturer
- In the survey participants' companies, serialization generally
 - Has high strategic priority (76%)
 - Is owned by the Supply Chain/ Logistics function (51%) or Manufacturing/ Ops function (29%)

Approach & Key ▼ Priorities

> Companies engage in serialization equally because of regulatory requirements, global strategy & a combination of the two

 Most companies require support in serialization by a 3rd party logistics provider (60%) Solution Requirements from 3PL

- 32% of manufacturers indicate need for serial number application & management by a logistics provider
- 48% of manufacturers indicate need for aggregation service



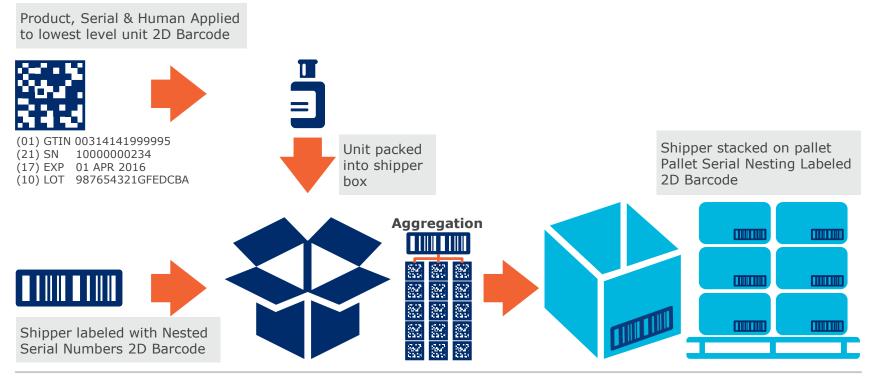


Serialization Solutions (1/2)



A 3PL can support manufacturers on serialization by application & management and/or tracking & validation

Serial number application & mgmt. Serial number tracking & validation









Four specific serialization solutions identified, all of them have system implications

Low	/ basic	Comprehensivenes	ss High		
Customer identified Solutions	1. Outbound scan capture	 Inbound capture outbound validation 	3. End to End serial number tracking	4. Serial number application & mgmt.	
Level of Tracking	No visibility to what or where serials are in the facility	Full visibility to what serials are in the facility	Full visibility to what and where serials are in the facility	Full visibility to what and where serials are in the facility	
EDI	Cutbound only	₹ ∎ Inbound/Outbound			
Transactions	Order Confirmation	Smart ASN Receipt Confirmation Order Confirmation (pot. Inventory Adjust.)	Smart ASN Receipt Confirmation Order Confirmation Inventory Adjustment	Smart ASN Receipt Confirmation Order Confirmation Inventory Adjustment Serial number mgmt	
Serial Number (S/N) capture	1 time capture	2-3 times capture & validation	3+ times capture & validation	Various models possible	
Aggregation	Optional	Optional as VAS	Must have	Must have	
	5	Application & management			







Due to lack of customer and/or legislative standard there are different local solutions in place

Low	/ basic	Solution	Comprehensivene	ss High
Customer identified Solutions	1. Outbound scan capture	 Inbound capture outbound validation 	3. End to End serial number tracking	4. Serial number application & mgmt.
Existing solutions within DHL Supply Chain	 US Italy Belgium Netherlands 	 Turkey Belgium Netherlands US 	• Brazil	 Netherlands Turkey Singapore UK UK Italy

Serial	number tracking
	& validation



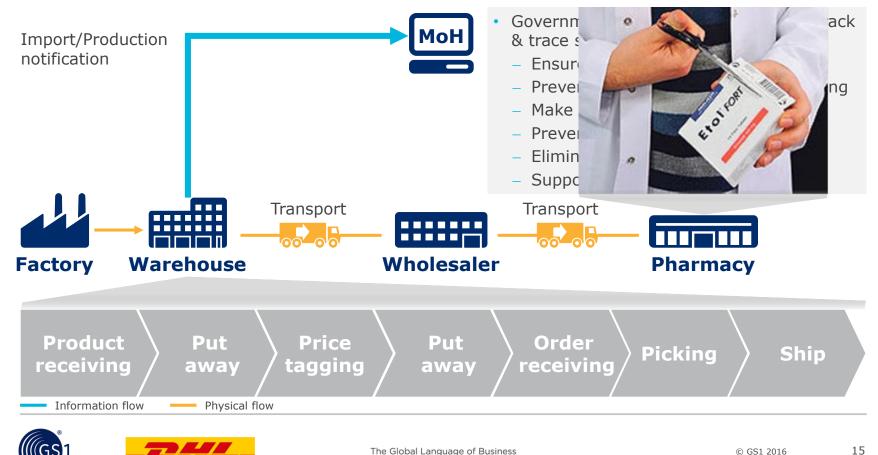




Deep Dive: Serialization in Turkey Situation Before Serialization



Notification an reimbursement process in Turkey before 2010 enabled fraud & double reimbursements



Deep Dive: Serialization in Turkey Implementation Phases



Track & Trace System in Turkey was implemented in two phases

TTS Project

Phase 1

Import/Production

Regulation demands

- 2D barcode application on individual box
- Management of 2D barcode data





Sales notification Regulation demands

- Hierarchy creation
- Sales Notification



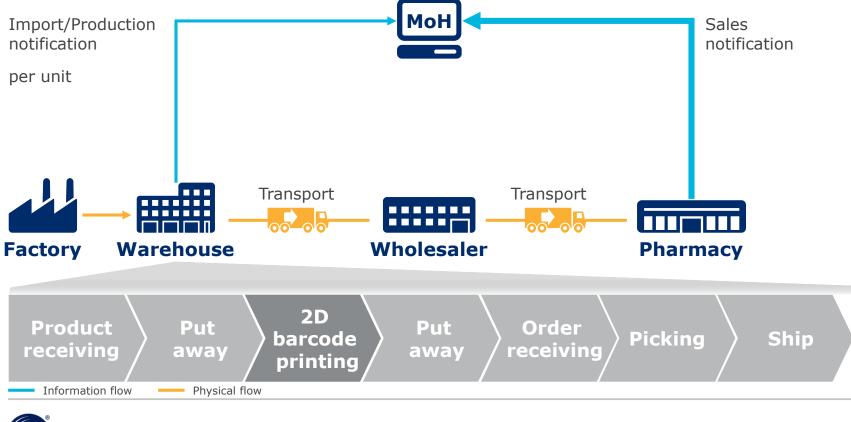




Deep Dive: Serialization in Turkey Process Amendments



Phase 1 focused on preventing fraud/ double reimbursements by introducing unit based sales notifications



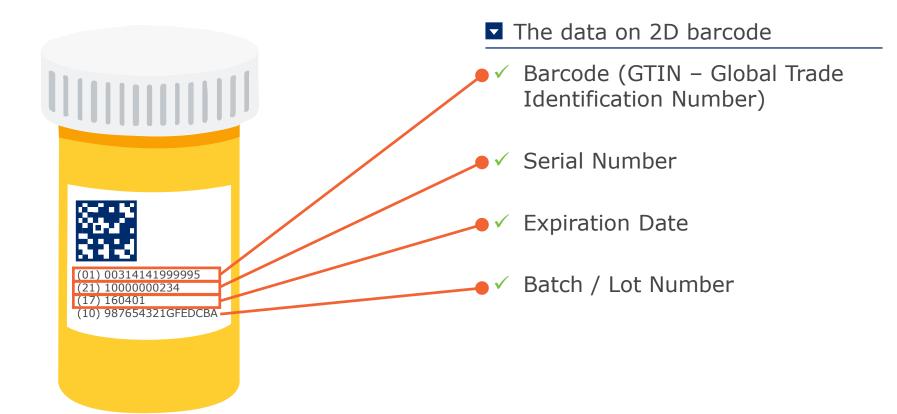




Deep Dive: Serialization in Turkey 2D Barcode



2D barcode printed on every packaged unit







Deep Dive: Serialization in Turkey Implementation Phases



Track & Trace System in Turkey was implemented in two phases

TTS Project

Phase 1

Import/Production

Regulation demands

- 2D barcode application on individual box
- Management of 2D barcode data









Phase 2

- Hierarchy creation
- Sales Notification



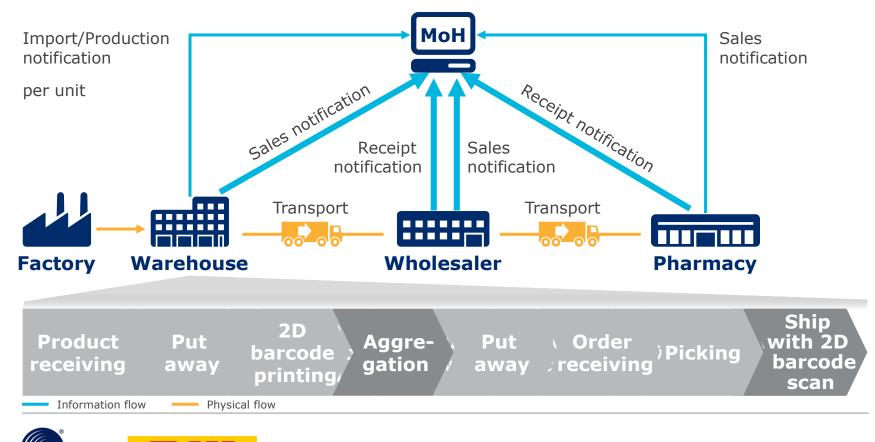
Deep Dive: Serialization in Turkey Phase 2: Process Amendments



© GS1 2016

20

Phase 2 focused on providing visibility where each produced/ imported unit is in the entire supply chain



The Global Language of Business

Deep Dive: Serialization in Turkey Customer Benefits



Our clients receive the supply chain services in full accordance with the legislations

- Reduced counterfeits, smuggled drug usage, scams & corruption
- Increased patient satisfaction & safety
- Improved customer competitiveness, reputation and market share
- Higher shipment precision
- Less time for placing orders required by using aggregations
- More efficient and effective sales analyses







Learning & Recommendations



Several aspects need to be considered when planning and implementing regulatory compliance projects

Business case

- Longer payback period (1.5 years)
- Justification based on legal requirements
- Take into consideration opportunity costs "What does it cost if I don't make the investment?"

Implementation

- Enter strategic partnerships with printing & labeling equipment
- Required additional bolt on solutions for issuing serial numbers and tracking additional levels of inventory

Change Management

- Relatively easy for 3PL to set up where postponement manufacturing is in existence with clean rooms and GMP trained people
- New processes around returns/recalls





Contact Information



Mike Meakin

Vice President – Global Quality & Regulatory Compliance Life Sciences & Healthcare, DHL Supply Chain

DHL Supply Chain

Brindley House, Eastern Avenue Burton on Trent, DE13 0BB United Kingdom

- **T** +44 (0) 1283 494203
- **D** +44 (0) 1283 494211
- **M** +44 (0) 7774 299402
- E Mike.Meakin@dhl.com

www.gs1.org







AmerisourceBergen Corp Serialized Pilots with EPCIS Jeff Denton, Sr. Director, Global Secure Supply Chain



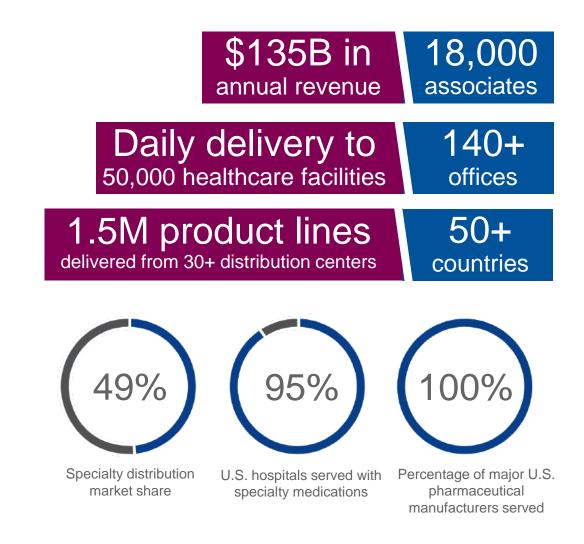
Today's Agenda

Voice of the Customer

Part 1	Getting to Know AmerisourceBergen
Part 2	The DSCSA Program
Part 3	AmerisourceBergen Approach
Part 4	Preparing for Serialization
Part 5	AmerisourceBergen Pilots
Part 6	HDMA Pilots



Getting to Know AmerisourceBergen AmerisourceBergen: By the Numbers





Structured for Solutions

• •	
Amerisou	rceBergen

Drug Corporation	Specialty Group	Animal Health	Global Sourcing & Manufacturer Relations
 Drug distribution to retail pharmacies, hospitals and alternate sites Good Neighbor Pharmacy services to independent pharmacies Product dispensing and packaging solutions Business coaching and consulting 	 Specialty drug distribution to physician offices, hospitals and alternate sites Practice efficiency solutions 3PL and clinical trial logistics Specialty pharmacy Global health outcomes Patient access and adherence services 	 Animal health product distribution Veterinary practice efficiency solutions Product dispensing and production animal management technologies VetOne private label animal health product portfolio 	 Global partnership development with pharmaceutical manufacturers Product sourcing and supply chain management across all channels PRxO Generics program management and operations



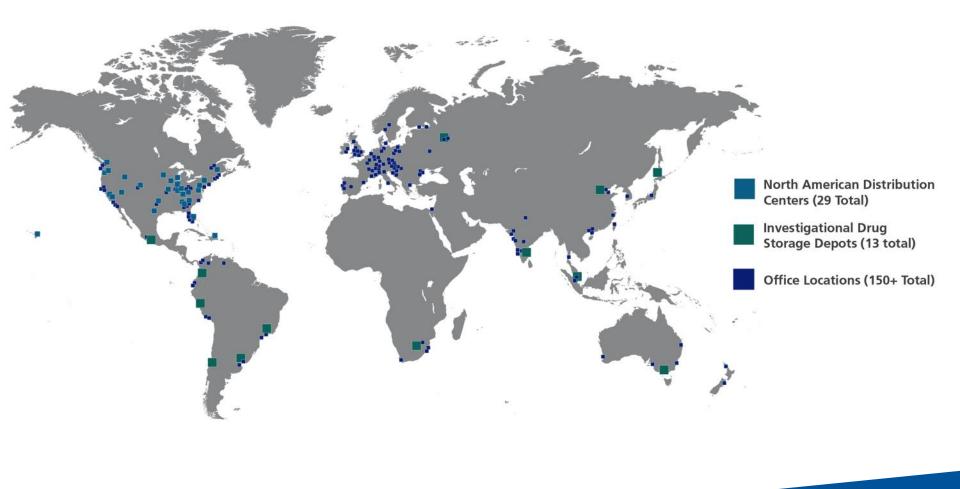
Business Units Impacted by DSCSA

And associated timeline

DQSA Expectations	Effective Date	AHP	Blue- point	ICS 3PL	ICS Title	ABSG	Onc. Supp	Drug	Thera Com Dist.	Thera Com Pharm.	US Bio	Central Fill
Transactional Information Provided by Manufacturer, Wholesaler and Re-packager	1.1.2015	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Suspect & Illegitimate products - SOP	1.1.2015	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Authorized Trading Partner	1.1.2015	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Transactional Information Accepted by Dispensers	7.1.2015		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Federal Licensure Standards Wholesale/3PL	2015	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			
Manufacturers Serialize	11.27.2017		\checkmark									
Re-packagers Serialize	11.27.2018	\checkmark										
Wholesalers Accept/Sell Serialized Product & Validate Serialize Number on Saleable Returns	11.27.2019	\checkmark			\checkmark	~	\checkmark	\checkmark	~			
Dispensers cannot accept product that is not serialized	11.27.2020									\checkmark	\checkmark	\checkmark
Complete Traceability	11.27.2023	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
29 4/18/2016 CONFID	ENTIAL									Ame	W risourc	eBerge

An Emerging Global Leader

Local Presence in 50+ Countries

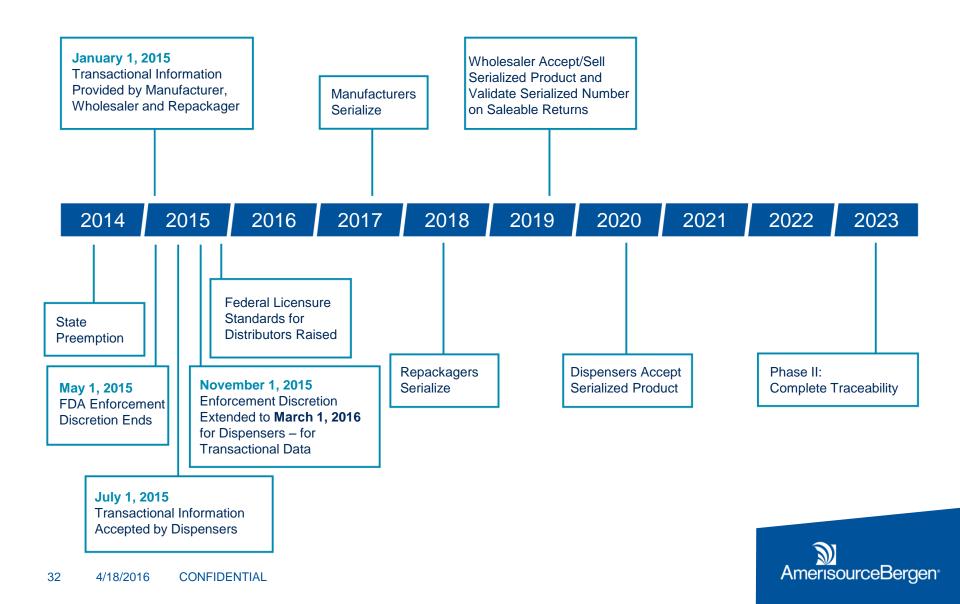




The DSCSA Program:



DSCSA Timeline – Phased Approach



AmerisourceBergen Approach

AmerisourceBergen's Architecture Design Principles

- Minimize storage of Lot and Serialization data in execution systems
 - Deploy a centralized repository of relevant data for the enterprise
- Downstream systems will be our internal "Scan Service"
 - Capture 2D information
 - Identify Biz Step involved with operational activity
 - Send both to enterprise system
 - Receive instructions for process and SNI disposition
- Centralized reporting solution
 - One ABC to our trading partners
 - One system of truth for legal immutable records
- One central system to provide data services
 - Lot and Serialized Event Capture
 - Data Query
 - Validation





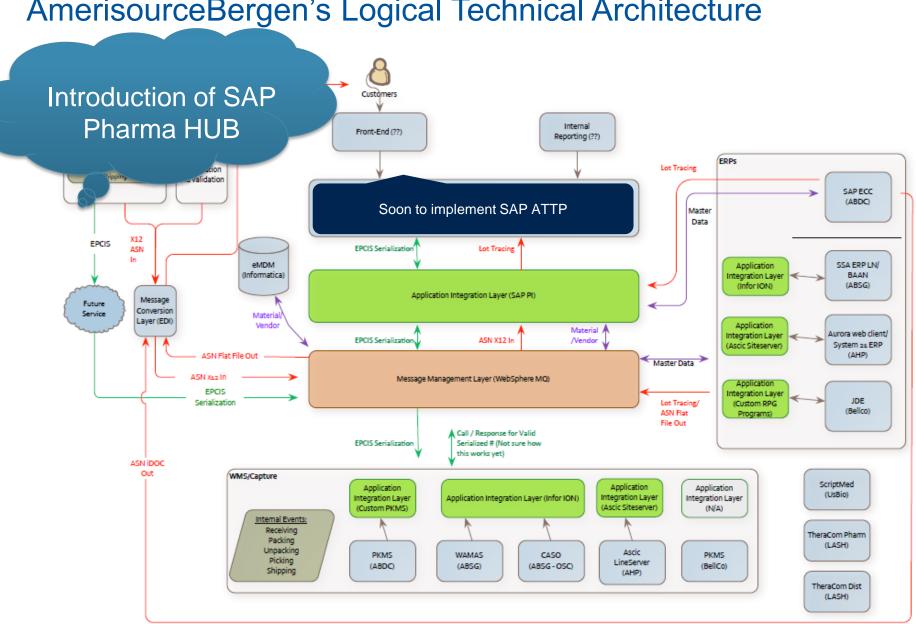
AmerisourceBergen's Architecture Design Principles

Continued

- Implement Enterprise MDM
 - One "source of truth"
 - Minimize interface file sizes
 - Maintain Data History
- Future Services from 3rd-party commercialized solutions
 - Data transformation
 - Trading partner set-up
 - Error handling and notification
 - Data pass-thru only, not transaction storage

SAP Pharm HUB





AmerisourceBergen's Logical Technical Architecture

Preparing for Serialization



Drug Supply Chain Security Act

Drug Wholesaler Upcoming Serialization Requirements



PRODUCT IDENTIFIER (2019). Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a **wholesale distributor** may **engage in transactions** involving a product only if such product is encoded with a **product identifier**.



VERIFICATION OF SALEABLE RETURNED PRODUCT (2019). [U]pon receipt of a **returned product** that the wholesale distributor intends to **further distribute**, before further distributing such product, the wholesale distributor **shall verify the product identifier**, including the standardized numerical identifier.



ENHANCED DRUG DISTRIBUTION SECURITY (2023). The transaction information required under this section **shall include the product identifier** at the package level for each package included in the transaction.



What's Next: 2019

Looking to the 2019 requirements for wholesalers



Engage in transactions involving serialized products (Rx)

- Visual confirmation of cases on receipt?
- Occasional audit of manufacturers; create tiered structure: trust but verify occasionally, audit every receipt?
- Catch additional issues upon receipt?

Associate saleable returned product with original product TI, TH, TS

- Our current business process is sufficient.
- If not...
 - > What enhancements should be considered or implemented.



Verify the product identifier for each saleable returned product (Rx)

- The term `verification' or `verify' means determining whether the product identifier -- affixed to, or imprinted upon a package or homogeneous case, corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer.
- How do we manage this?



What's Next for DSCSA? 2019 Saleable Returns

What is the impact to AmerisourceBergen

Saleable return units/year 15,259,042 (97% OF ALL RETURNS)

NUMBER OF SALEABLE RETURNS ACROSS NETWORK ${\sim}62,000/day$ & 115,000/day peak

ABDC peak # of saleable return units/day for each DC ~ 4.500

ABDC peak # of saleable return units/day for larger DCs $\sim 10,000$

ABSG avg # of saleable return units/day for ABSG

~200

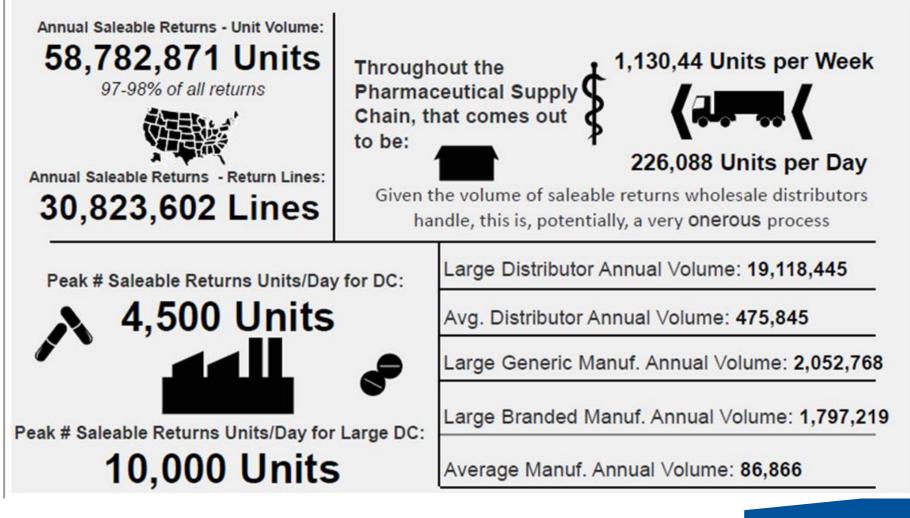
No established industry solution to manage serialized returns



*data from June 2014 to June 2015

Industry Returns Volume

Looking to the 2019 requirements for wholesalers





What is activity planned in 2016 at AmerisourceBergen

- Implementing SAP ATTP & SAP Pharma Hub
 - Conversion from OER
- AmerisourceBergen and HDMA Managed Trading Partner Pilots
 - EPCIS TI, TH, TS Data Exchange Proving and testing out the migration from ASN to EPCIS for exchange of TI, TH, TS data ~ Calendar year Q2 2016.
 - End-to-End Pilot Exception handling, in-network serialized product movement ~ Calendar year Q4 2016
- Customer Requirement Gathering
 - Begin serialization education with key strategic customers.
 - Identification and gathering of customer serialization requirements and potential capabilities.



AmerisourceBergen Pilots



2015 ABC Serialization Pilots

Revisiting ... What is Success?

Business & Process



Ability to receive, pick/pack, and ship serialized product... 2023 happy path
 Scan/Capture or Compare/Match serialized data (no data, aggregated data)
 Establish label review and confirmation processes

Technology

- ✓ EPCIS integrations with Trading Partners for exchange serialized data
- ✓ Automation Technology functional in pick processing @ acceptable rates
- Enterprise S/N transaction system installed & tested for function and latency

Industry

Capture data & metrics; analyze to determine future data expectations

Establish templates & engagement mechanism for future pilots



2015 ABC Serialization Pilots

Initial Data Collection Summary

Total # of Serialized Products Received (in EPCIS) ~ 143,000 Total # of Scanned Receipts (SSCC, Case, Each) – 1,657 Total # of Scanned Pick/Pack/Shipments (Case, Each) – 52,636 Serial Numbers Scanned (Receipt/Ship) by ASD: 206 / NA* Serial Numbers Scanned (Receipt/Ship) by OSC: 973 / 49993 Serial Numbers Scanned (Receipt/Ship) by NDC: 356 / 731 Serial Numbers Scanned (Receipt/Ship) by FDC: 149 / 1947

2015 ABC Serialization Pilots

Key areas of learnings

Data Exchange

- Every manufacturer had at least one issue with serialized data exchange (Product before data, data syntax errors, manufacturer IT errors, etc)
- Product Labeling
 - Identified issues with pallet, case and each labeling
- Operational Impact
 - Varying degrees of impact on receiving, manual picking & automation; impact driven by what level of scan required
- Solution Testing
 - Using real world processes, data and products identified additional issues



HDMA Pilots



Pilot Objectives

- Provide data to the FDA to illustrate the realities faced by manufacturers and wholesalers in processing DSCSA compliant returns
- Demonstrate that manufacturers and wholesalers are taking the DSCSA Requirements seriously, and are actively working to incorporate these into the daily routine
- Illustrate to the FDA and other members of the supply chain the relative practicality of possible solutions
- Begin the process of building consensus on likely approaches that will work without adding significant burden to the supply chain



Return Scenarios;

- Manufacturer sends to wholesale distributor product identifiers for only the units purchased by the wholesale distributor
- Manufacturer sends to all wholesale distributors product identifiers for all units (not just the product identifiers for the units purchased by the wholesale distributor)
- Central repository all manufacturers send data to database, automatically verified
- Verification service each manufacturer has a database where the service will check against the external database automatically, connecting through an interface
- Portal each manufacturer has their own verification database (manual without a verification service)
- 6. Distributors scan product on inbound
- 7. Distributors scan product on outbound
- Distributors manually confirm with manufacturers at time of return via phone or email
- Verification Discovery Service router to link to the databases (Like number 4 but with router service / server)

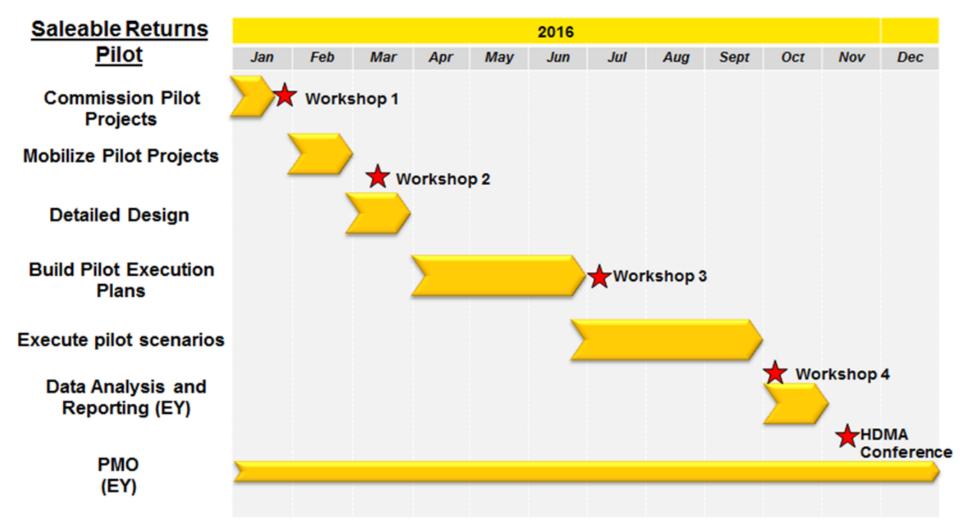


Pilot Methods for each scenario

Approach	Methods to verify saleable returns
Live Pilot	 Manufacturer sends to wholesale distributor product identifiers for only the units purchased by the wholesale distributor (scenario 1*). Central repository: All manufacturers send data to a central database, automatically verified (scenario 3). Distributors scan product on outbound (scenario 7).
Desktop (Future workshop)	 Verification service - each manufacturer has its own database, check external database automatically, connect through an interface (scenario 4) Portal - each manufacturer has its own - manual without a verification service (scenario 5) Verification Discovery Service - router to link to the databases (scenario 9)
White- paper (No workshop)	 Manufacturer sends to all wholesale distributors product identifiers for all units (not just the product identifiers for the units purchased by the wholesale distributor) (scenario 2) Distributors scan product on inbound (scenario 6) Distributors manually confirm with manufacturers at time of return via phone or email (scenario 8)



Timeline/Roadmap





AmerisourceBergen[®]

Where knowledge, reach and partnership shape healthcare delivery.

MCKESSON

Wholesaler Implementation GS1 Global Healthcare Conference Dubai, UAE April 18, 2016

McKesson Distribution Solutions

- U.S. Pharmaceutical
- McKesson Canada
- Celesio (Europe and South America)
- McKesson Medical-Surgical
- McKesson Specialty Health
- McKesson
 Pharmacy Systems
 and Automation
- * McKesson Packaging Solutions

McKesson Technology Solutions

- McKesson Health Solutions
- Imaging and Workflow Solutions
- Connected Care and Analytics
- Business Performance Solutions
- Enterprise Information Solutions

M^CKESSON

McKesson is an industry leader in:

- Pharmaceutical distribution in the U.S. and Canada
- Medical-surgical distribution to alternate care sites
- Generics pharmaceutical distribution
- Medical-management software and services to payers
- Business and clinical services for providers
- Connectivity services



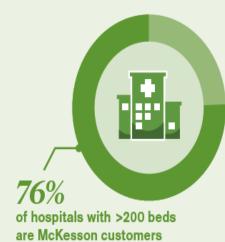




used each day in North America are delivered by McKesson

largest pharmacy chain

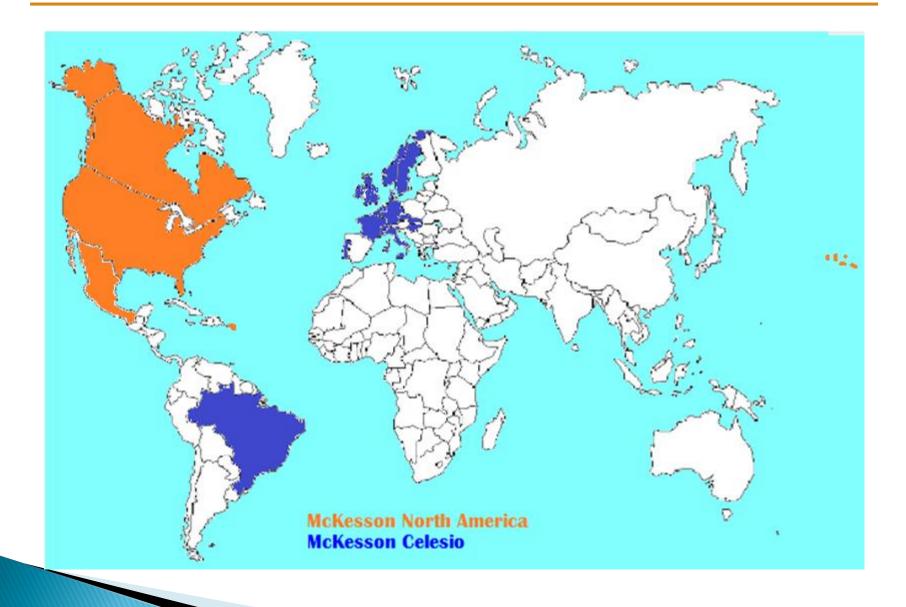
3,000+ retail pharmacies are members of our Health Mart® franchise



100%

of the top 25 health plans are McKesson customers

M^CKESSON



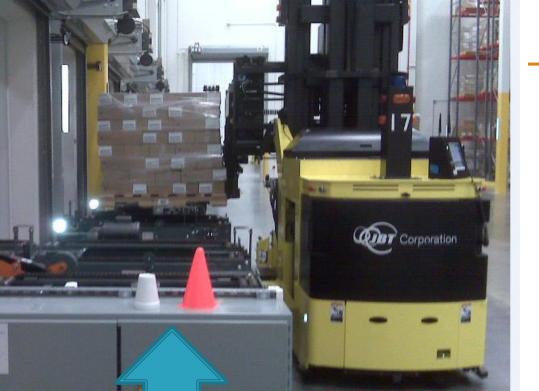


Receiving

Traceability Data is received from shipper, stored and used to match Receiving scans

Cases aggregated to pallets

Pallets, Barcoded Case and Each (GS1–128, GTIN12 & 2D Data Matrix)



M^CKESSON

Putaway

Pallets placed in bar coded rack locations

Pallets retrieved from Receiving with SSCC



Case Pick Scan





Aggregation of cases





Each Putaway





Each Pick Scan to Tote





Aggregation of Totes



M^cKESSON

SSCC Containers Staged to Ship



Traceability Data is created by distributor and sent to pharmacy

Facilitates delivery tracking and digital receiving by pharmacy



Business case

- Compliance
- Process Improvement
 - Patient Safety through Order Accuracy
 - Inventory Shrink Reduced to 0.00147%



Where to start

- Consistent methodology for multiple product lines (Prescription, Over the Counter, Devices)
- Broad appeal to up and downstream partners
- Leads to GS1 Standards



Driving change in distribution

- Embed into processes
- Use GS1 bar codes where possible to eliminate error and confirm product

Learnings

- Master data challenges will exist when you start
- Consistency in segment expectations speeds adoption
- Track & Trace and Verification may use the same standards for encoding product but operationally are much different from each other



Benefits/Future Path

- Serialization with Traceability will increase control on returned product.
- Serialization will allow verification
- Serialization can provide clarity over inventory adjustments





Scott Mooney Vice President Distribution Operations -Supply Chain Assurance McKesson Corporation

scott.mooney@mckesson.com