



The Global Language of Business

GS1 standards for moving products through the supply chain

Jeff Denton, Global Secure Supply Chain, Amerisourcebergen, US



Today's presenters



- Heather Zenk, SVP, Secure Supply Chain & Replenishment Operations, Amerisourcebergen, US
- Mike Meakin, VP- Global Quality Regulatory & Compliance, DHL Supply Chain, UK
- Scott Mooney, Vice President Distribution Operations, McKesson, US



Our agenda



- 5 min introduction – Jeff
- 15 min presentation - Heather
- 15 min presentation – Mike
- 15 min presentation – Scott
- 25 min Q & A – Facilitated by Jeff
- 5 min close – Jeff

Please be ready with your questions!

GS1 Standards for Moving Products Through the Supply Chain

Heather Zenk, SVP, Replenishment & Secure
Supply Chain Operations, RPh, PharmD,

April 2018

Serialization

Agenda

Part 1	ABC – Who Are We
Part 2	Importance of Interoperability
Part 3	Issues within current processes
Part 4	Removing the ambiguity and what “Will Be”

Structured for success

AmerisourceBergen

Steve Collis, Chairman, President and CEO

Pharmaceutical Distribution & Strategic Global Sourcing

Bob Mauch, Group President

Combines all of our strategic sourcing, distribution and provider-facing solutions to drive value, access and quality in patient care

- Drug distribution to all sites of care
- Outsourced compounded sterile preparations
- Operational effectiveness technologies and consulting for health systems, practices and pharmacies
- Market and consumer engagement services for pharmacies and practices
- Specialty physician GPOs
- Specialty pharmacy
- Product sourcing, supply chain management and global manufacturer partnership development
- PRxO Generics purchasing program

Global Commercialization Services & Animal Health

Jim Cleary, Group President

Extends impact of our commercialization expertise to create more integrated delivery. Combined with animal health to produce tighter coordination across human and animal health

- Global specialty logistics from clinical through commercial
- Global health outcomes and market access consulting
- Patient access and adherence services
- Integrated solutions for key international markets
- Animal health product distribution
- Veterinary practice efficiency solutions
- Product dispensing and production animal management
- VetOne private label animal health product portfolio

Maximizing our impact at the center of healthcare delivery

Pharma Manufacturers

Product sourcing, distribution and commercialization services across all product types, including:

- Brand
- Generic
- Specialty
- Biosimilar
- Over the counter (OTC)
- Medical devices



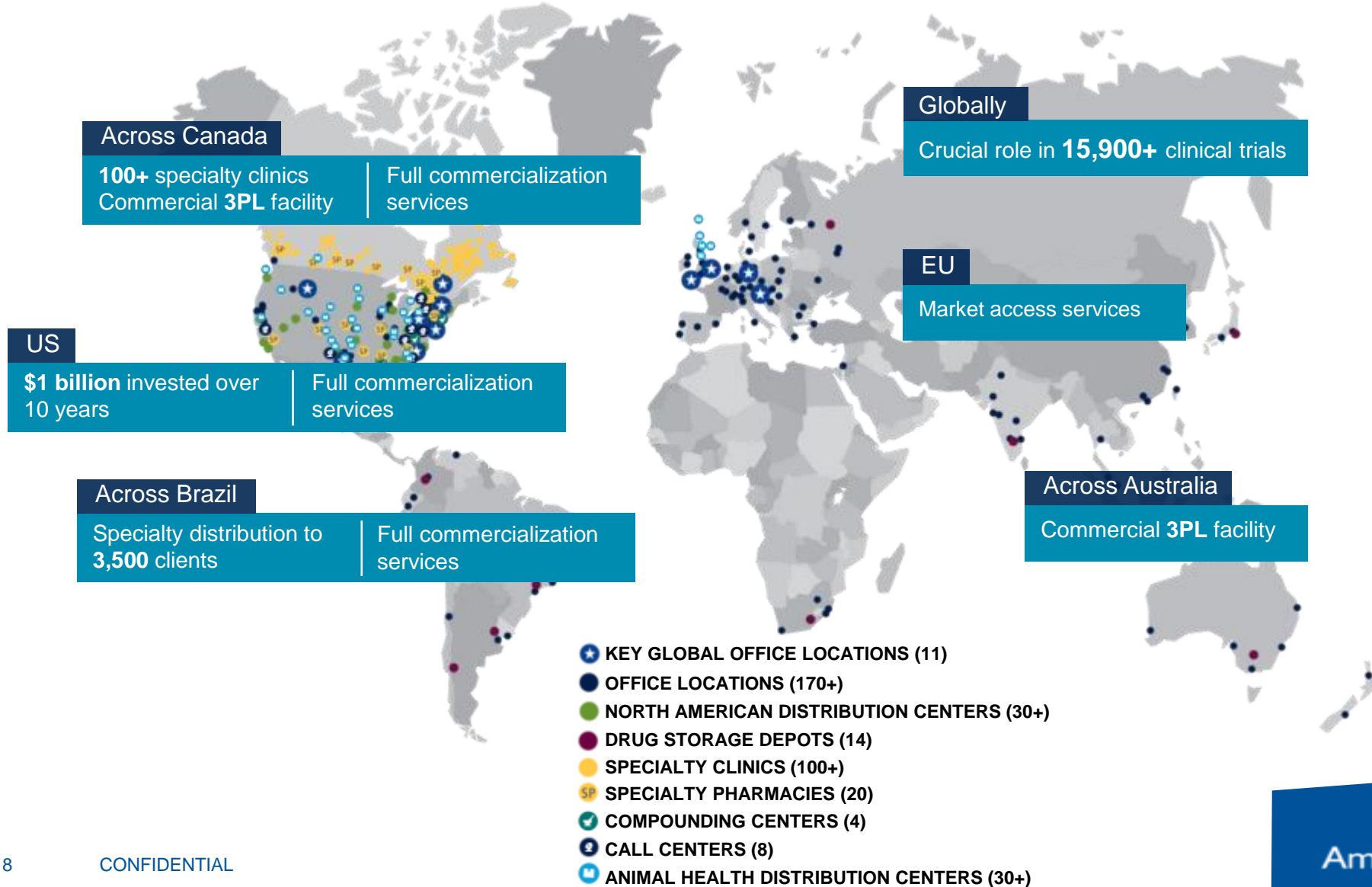
Healthcare Providers

Providing pharmaceuticals, healthcare products and business services that enable quality care across all sites, including:

- Community and independent pharmacies
- Specialty pharmacies
- Pharmacy benefit managers (PBMs)
- Health systems
- Alternate sites of care
- Physician practices
- Veterinary clinics
- Livestock producers and animal health dealers

Expanding global market opportunities

Bridging human and animal health



Our company: By the numbers

\$153B



**2017
Revenue**

Growth aligned with
our customers'
long-term success

21,000+



**Company
Associates**

Diverse expertise all
focused on improving
global health

150+



**Global
Offices**

Delivering a range
of services to
address specific,
local needs

50+



**Countries with a
Local Presence**

Growing knowledge
of market-specific
healthcare
environments

The importance of interoperability

- ABC processes hundreds of thousands of transactions shared with and between trading partners each business day
 - Manufacture PO's/Invoices, Shipment Notice/Advice, Credits, Return Authorization, Chargeback/Rebates, Customer PO/InvoicesCurrent VIA Electronic Data Interchange, etc.
 - EDI Is used for 99.99% of all transaction interactions
 - Have been interoperable with the use of standards in electronic transactions for 35+ years
- Interoperability has been made possible with the use of Standards
 - Transaction sets; primarily ANSI X12 Format
 - Defined field content within electronic transactions
 - Provides predictable content for processing

Issues with current processes that plague our supply chain

- Product Identification
 - NDC Number is used in the US for broad product identification
 - Does not represent pack or case size
- Product Markings on Case or Outer-pack
 - Multiple Bar Codes
 - Multiple placements of labels
 - Multiple placement of label content
- Trading Partner Identification
 - Multiple identifiers are used including DEA, DUNNS, HIN, State License Number
 - Identifier does not always represent the exact location within a physical building, ie. Hospital Pharmacy versus Hospital Outpatient Clinic
 - Names and ownership can change frequently across customer base
- ANSI X12 Datasets
 - Multiple “maps” of each transaction are required to meet the needs of our trading partners

Removing the ambiguity - GS1 standards will resolve our issues

- Product Identification
 - GS1 Global Trade Identification Number (GTIN) will replace the use of NDC
 - Provides exact product identification, including pack/case
 - Product Markings on Case or Outer-pack
 - Provides universal specification for Bar Code use and content
 - US is migrating to GS1 2D Data Matrix Bar Code on all Pharmaceutical Products
- Trading Partner Identification
 - GS1 Global Location Number (GLN) will replace the use of multiple
 - GS1 GLN's can be very specific in location identification for ordering, billing, shipping as well as changes in ownership
- EPCIS
 - GS1 Electronic Product Code Information Services (EPCIS) will be used for regulatory transactions
 - No adjustment to format required removing the need for variable maps

What Standards can do!



- Unit Level: Assign a unique serial number to each saleable unit and case with GS1 2D Standardized format.



- Case Level: Encode the GTIN, serial number, expiration date, and lot number in a 2D GS1 DataMatrix.

Moving to a serialized world

It's an opportunity to go from this...



Moving to a Serialized World

To this...



The Drug Supply Chain Security Act

November 27, 2017 Requirements -- **Enforcement Discretion to 2018**

- Manufacturers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.
 - The serialized barcode contains the following data elements: a product identifier, serial number, lot number and the expiration date.
- Global Trade Identification Number (GTIN).
- Serial Number (SNI).
- Lot (Batch) Number.
- Expiration Date.



Global Trade Identification Number (GTIN)
Serial Number (SNI)
Lot (Batch) Number
Expiration Date



Where knowledge,
reach and partnership
shape healthcare delivery.

GS1 STANDARDS FOR MOVING PRODUCTS THROUGH THE SUPPLY CHAIN

GS1 Healthcare Conference

**Mike Meakin, Vice President, Global Quality Regulatory & Compliance
Bogota, 10 April 2018**

DHL Life Sciences & Healthcare



Agenda – GS1 standards providing products through the Supply Chain

- DHL – Company background and GS1 Relationship
- Primarily Serialization Solutions/History and Global focus with pharmaceuticals
- Global Regulations/Current Challenges
 - Medical Devices UDI
 - Procurement NHS SC
 - GLNs for NHS SC and Serialisation
 - Clinical Trials
- Supply Chain Designs – Blockchain
- Hospitals Patient Transport/Inventory Stock control
- Transport/Logistics Sector overlap



DHL – GS1 relationship long standing between GS1 and DHL

▼ DHL/NHS 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 work together

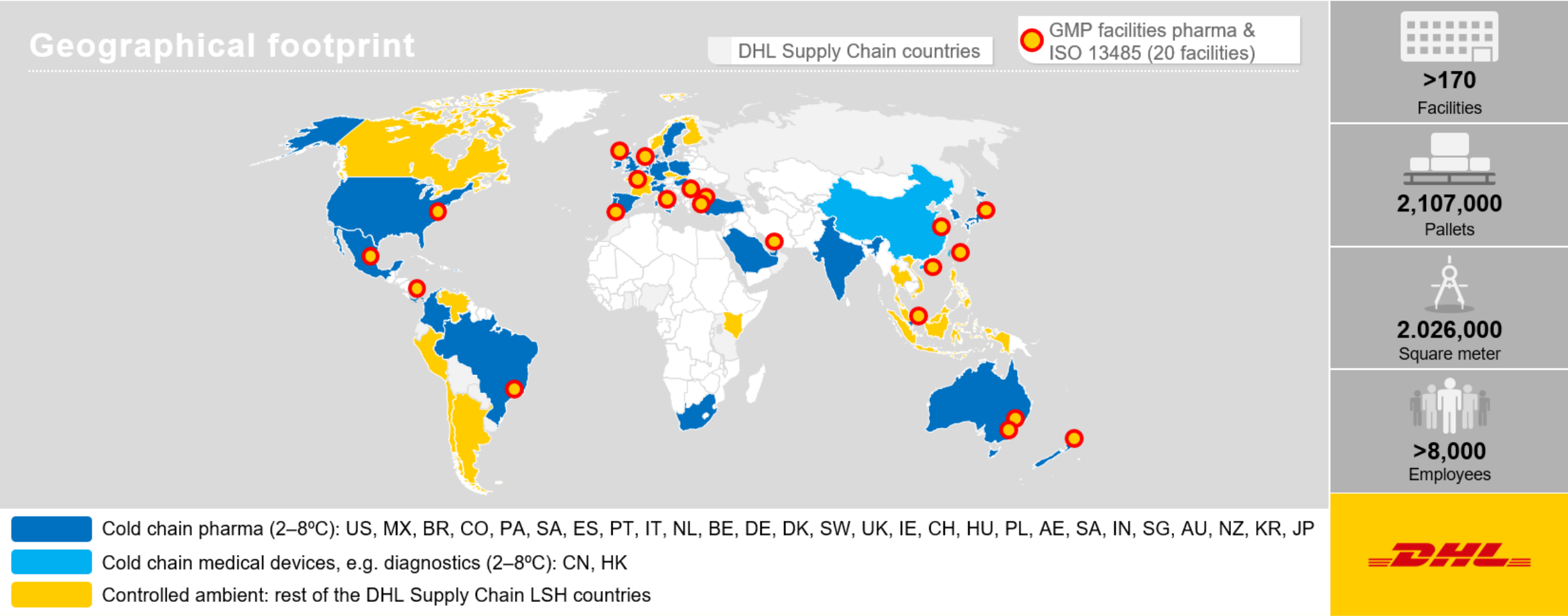
- 10+ years with GS1 Healthcare Sector Voting Member
- CEO John Gilbert on GS1 Board
- Mike Meakin HLT
- CEO NHS SC Nick Gerrard on UK Healthcare Advisory Board
- APAC CEO DGF Kelvin Leung on GS1 HK Board
- Member of Transport & Logistics Sector
- Using GS1 standards

▼ GS1

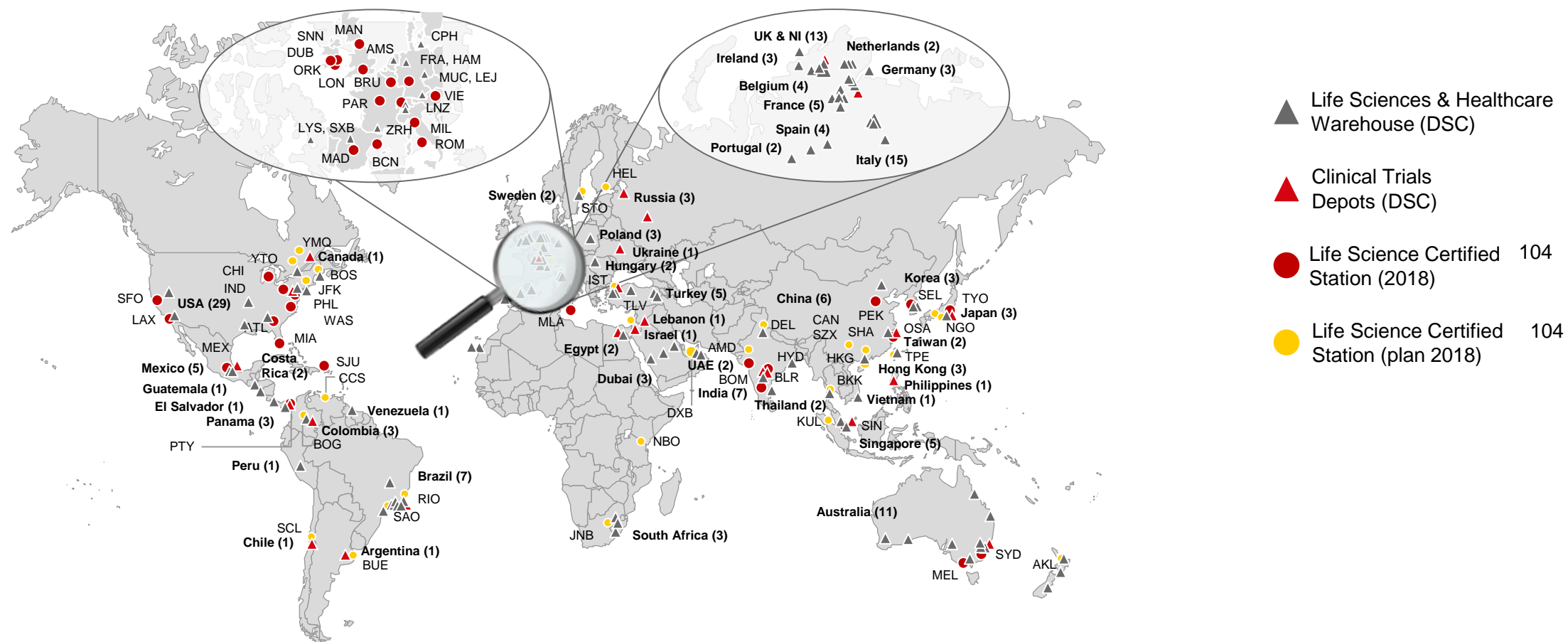
- 111 member organizations
- Member driven
- 150 countries served
- 20 different domains
- 2,500 people helping us
- Over 6bn transactions a day
- 38 HUG Countries



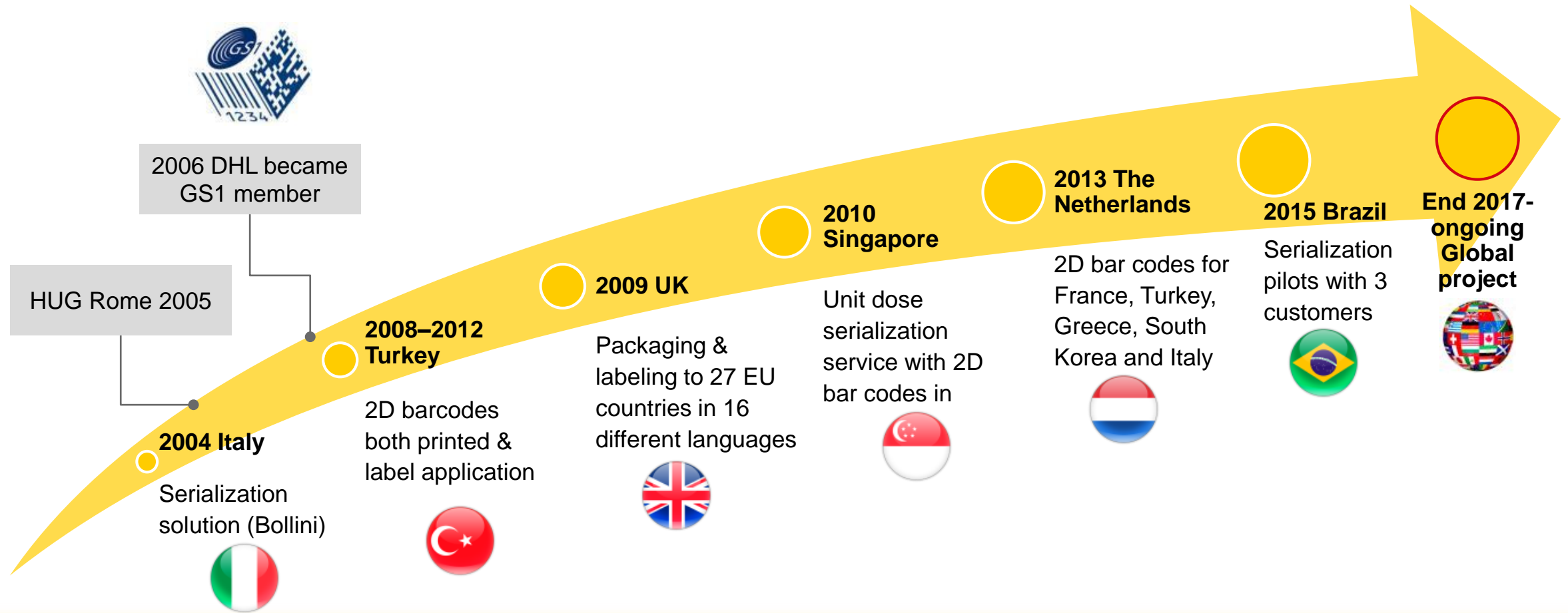
DHL Supply Chain – Life Sciences & Healthcare GMP network



A global network of DHL facilities focused on Life Sciences & Healthcare










DHL Serialization journey

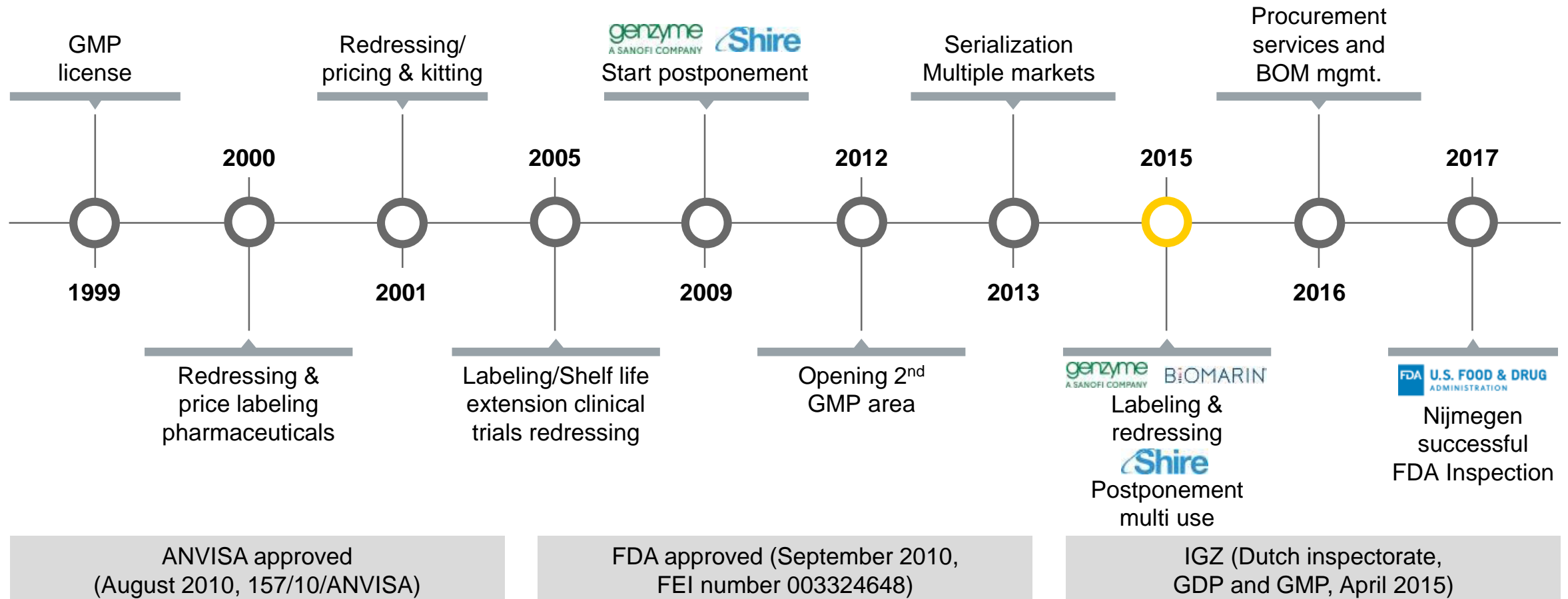


3PL IT serialization solutions

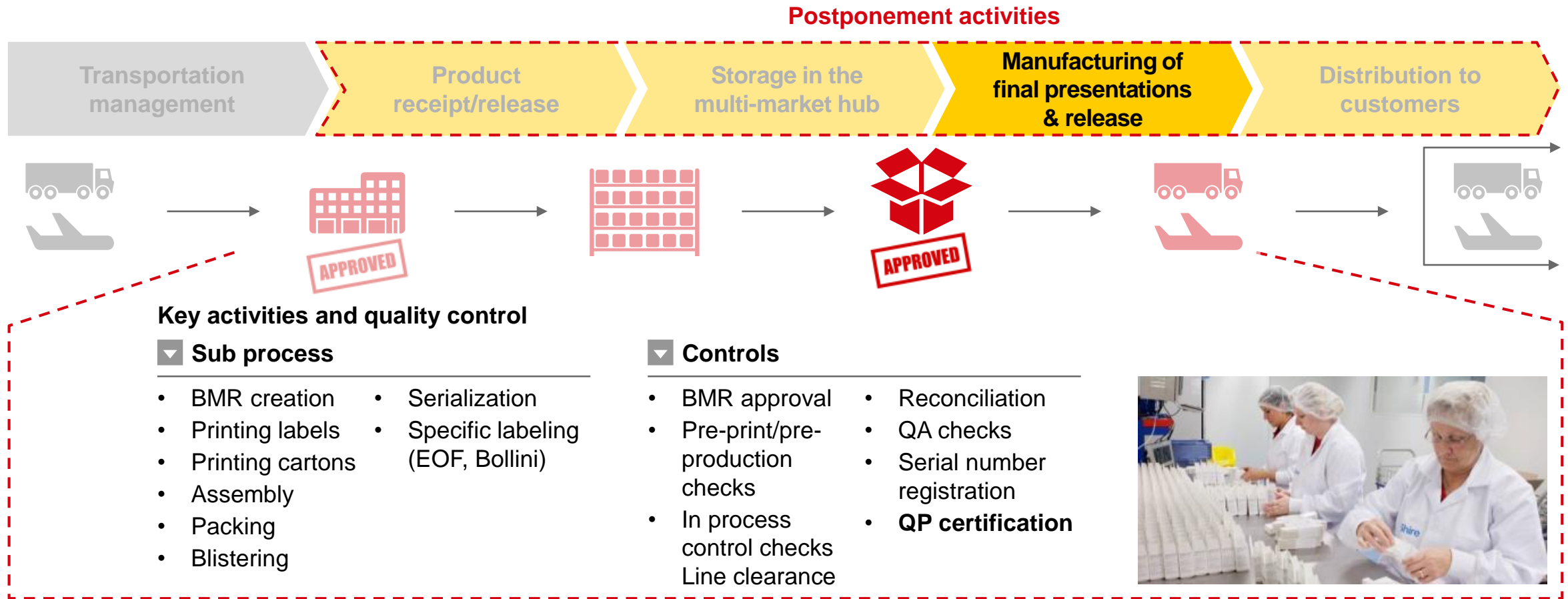
Four specific serialization solutions identified, all of them have system implications

	Solution Comprehensiveness			
	Low/basic			High
Customer identified Solutions	1. Outbound scan capture	2. 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	 Outbound only	 Inbound/Outbound		 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
	Serial number tracking & validation			Application & mgmt.

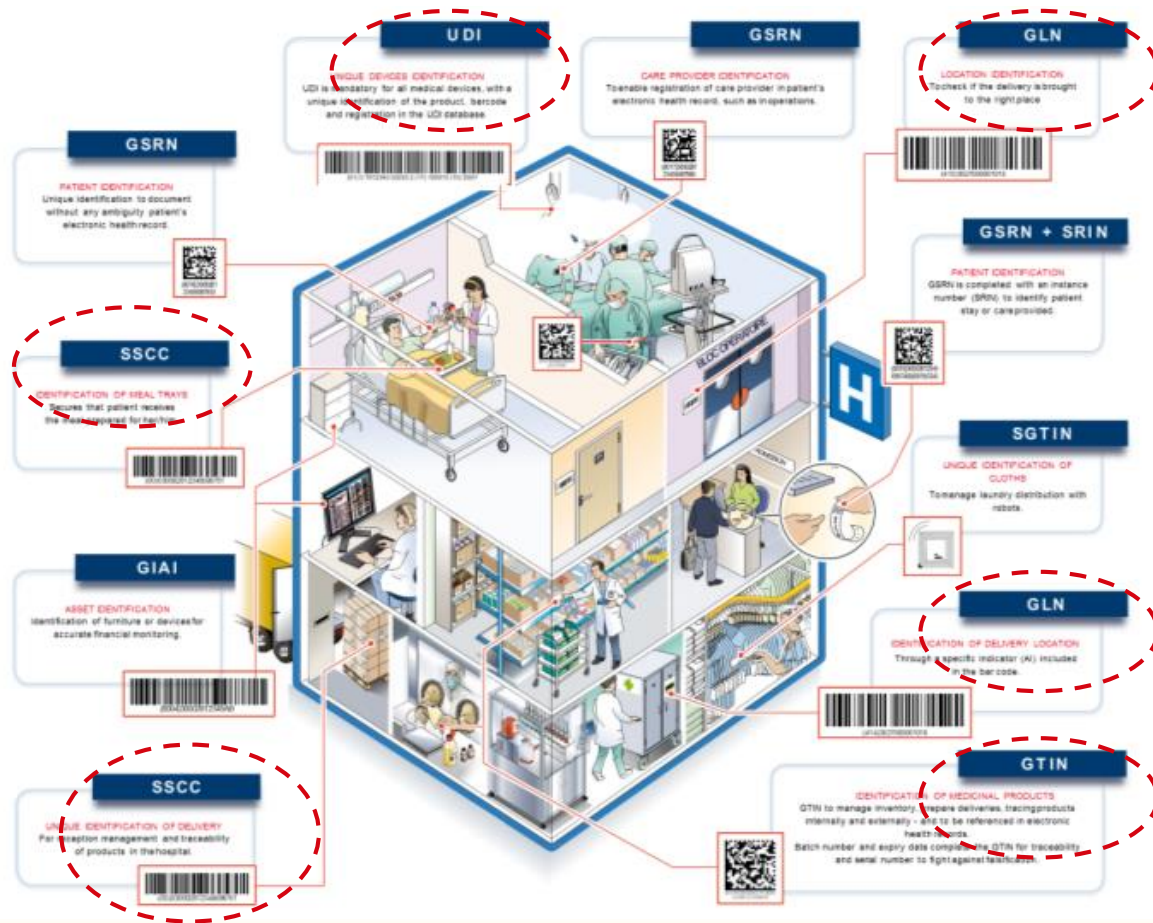
Example of site journey – Postponement capabilities in Nijmegen



Postponement – Overview of key activities



The GS1 standards to ensure traceability and patient safety



copyright GS1 France and GS1 Switzerland - 2016



DHL recognizes there are further improvements to come with bar codes



50,000 patient movements per month
20,000 patients for dialysis
7,000 outpatients
275 bariatric movements per month

Questions and Contact information



ISO 13485 ISO 14001 ISO 22301 ISO 27001

Mike Meakin

Vice President
Global Quality, Regulatory & Compliance
Life Science & Healthcare

Phone +44 (0) 1283 494211

Mobile +44 (0) 7774 299402

Fax +44 (0) 1283 494237

mike.meakin@dhl.com



Supply Chain

DHL Supply Chain
Brindley House
Eastern Avenue
Burton on Trent
DE13 0BB
United Kingdom

www.dhl.com



GS1 Standards in Use at McKesson Corporation Globally

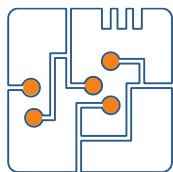
Scott Mooney, Vice President Distribution Operations

McKesson Corporation

GS1 Global Healthcare Conference

Bogota, Columbia

April 10, 2018



*Healthcare is getting
more high tech*

*Populations are getting
older around the world*



*Chronic diseases
are more
common*



Healthcare is changing rapidly

*Consumers
have more
power*



*Value-Based Care is here
and continues to prevail*



*Governments & regulators
continue to rewrite
the rulebook*

We Make Better Health Possible

A close-up, profile view of a newborn baby with dark hair, looking upwards. The baby is being held by a person whose arm and shoulder are visible, wearing a blue shirt. The background is blurred, showing another person's face in the distance.

From delivering life-saving medicines to helping our customers and partners solve their problems, everything we do is to improve lives by making better health possible.

We're Proud of Where We Are Today

We have **75,000+**
employees in 16+ countries

Our FY17 revenues
were **\$199B¹**



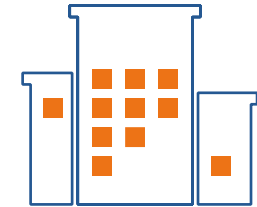
We serve
2M+ customers each day
across 13 European countries

Specialty Leader

We support
9,100+ oncologists
& other specialists



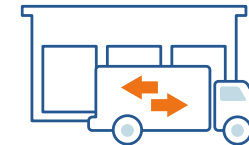
We're a Fortune 5 & 'Most Admired' company



We support
15,000+
owned and banner
pharmacies



We offer **250,000+**
SKUs of brand &
private label
medical-surgical
supplies



We deliver **1/3 of**
prescription
medicine
in North America²

¹Financial data reported for Fiscal Year ended March 31, 2017. Operational and employee data reflected as of March 31, 2017.

²This information is an estimate derived from the use of information under license from the following IQVIA, formerly Quintiles IMS, information service: Market Prognosis North America for the period 2017-2021 (published March 2017). Note: IQVIA expressly reserves all rights, including rights of further copying, distribution and republication. McKesson does not warrant or represent the accuracy of IQVIA data or McKesson's interpretations of IQVIA data. Any subsequent use or interpretation of this data will be the liability of the receiving party and not of McKesson or IQVIA.

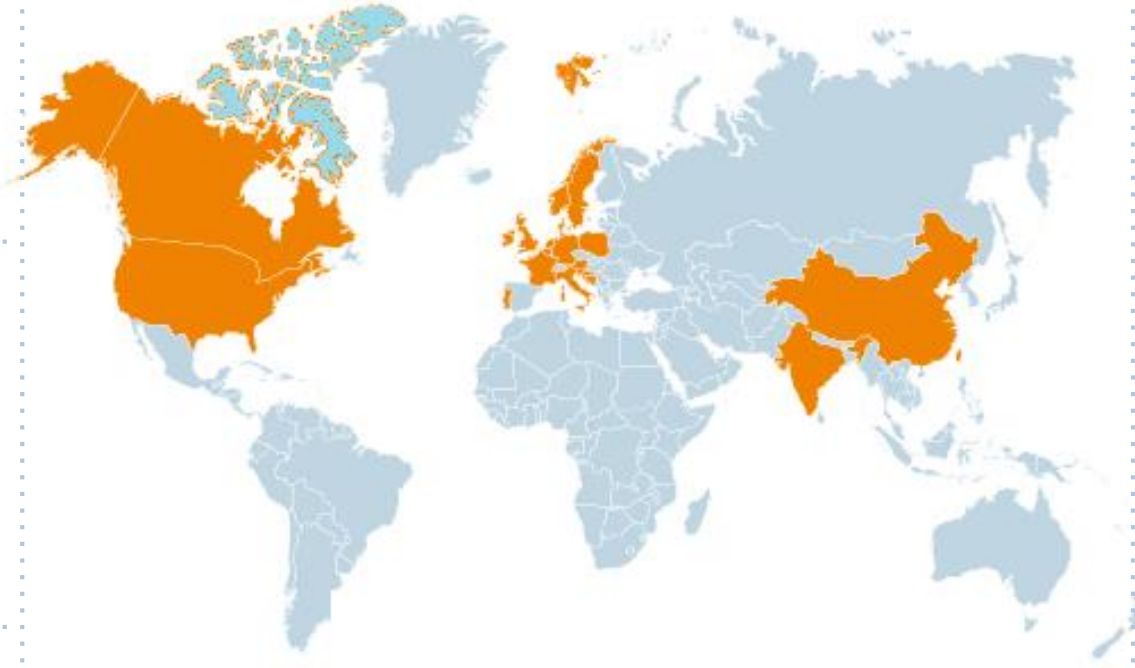
Supply Chain Excellence

We strive for perfection with
99.98% order accuracy
in North America

Together with Walmart,
we're creating more value
for customers & patients



We take efficiency to the
highest level with
6σ McKesson
Six Sigma



*We take a **global approach***
to procuring and sourcing
our products

We keep costs down and
efficiency high with our own
generic drug, medical supply
and over-the-counter
private labels



We supply and operate
pharmacies around
the world

Pharmacy

Delivering closer patient relationships

We help pharmacies spend more time with patients and less time worrying about the everyday nuts and bolts of running a business. We have solutions for just about anything that gets in the way of that.



15,000+

owned and banner pharmacies



Canada:
~2,500 owned and banner



United States:
>4,800 Health Mart stores



Europe:
>8,100 owned and banner



LloydsPharmacy

Guardian

Rexall

Remedy's Rx.

gesundleben

Careway

Biologics

vitusapotek+

Pharmactiv

Proxim

CLINIQUE
Santé

Sainsbury's

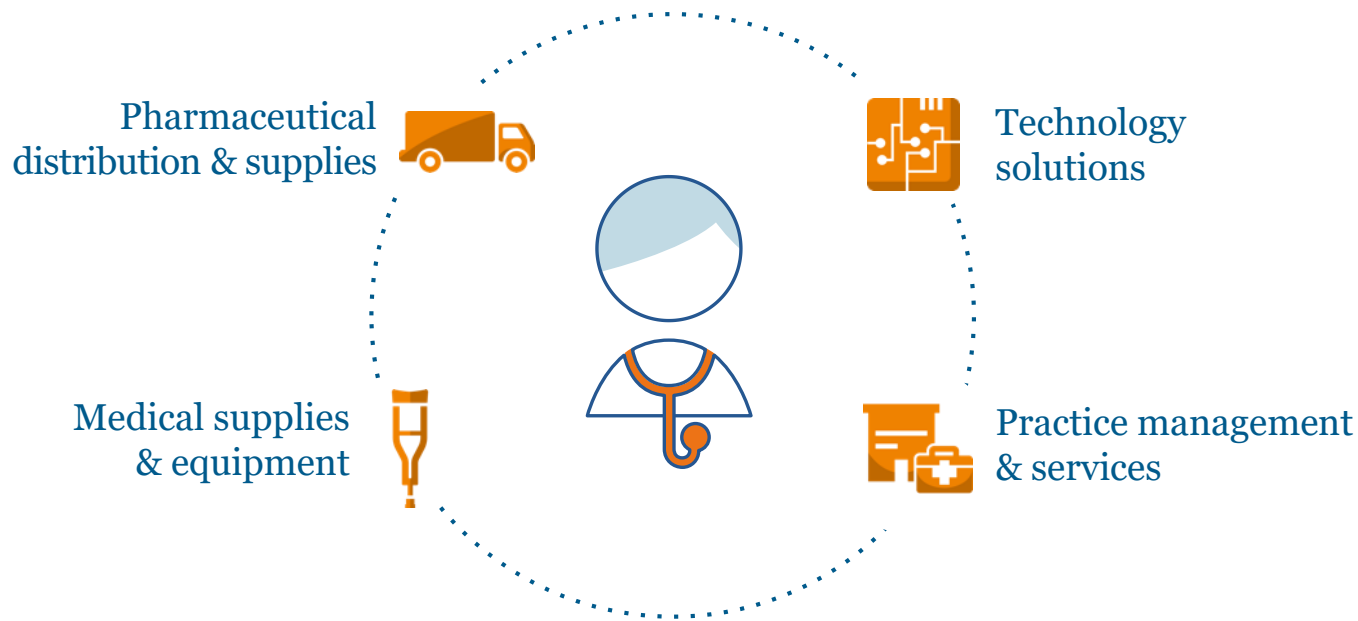
Euniprix

I.D.A.

Community Providers

Delivering more time for patient care

Because we know most providers aren't passionate about back-end administration, our focus is helping them gain more time to do what they actually love — deliver the best possible care to improve lives.



Specialty Leader

> **1.3M prescriptions**
dispensed in the U.S. each year *

> **3,700 Oncologists**

> **5,350 other specialists**



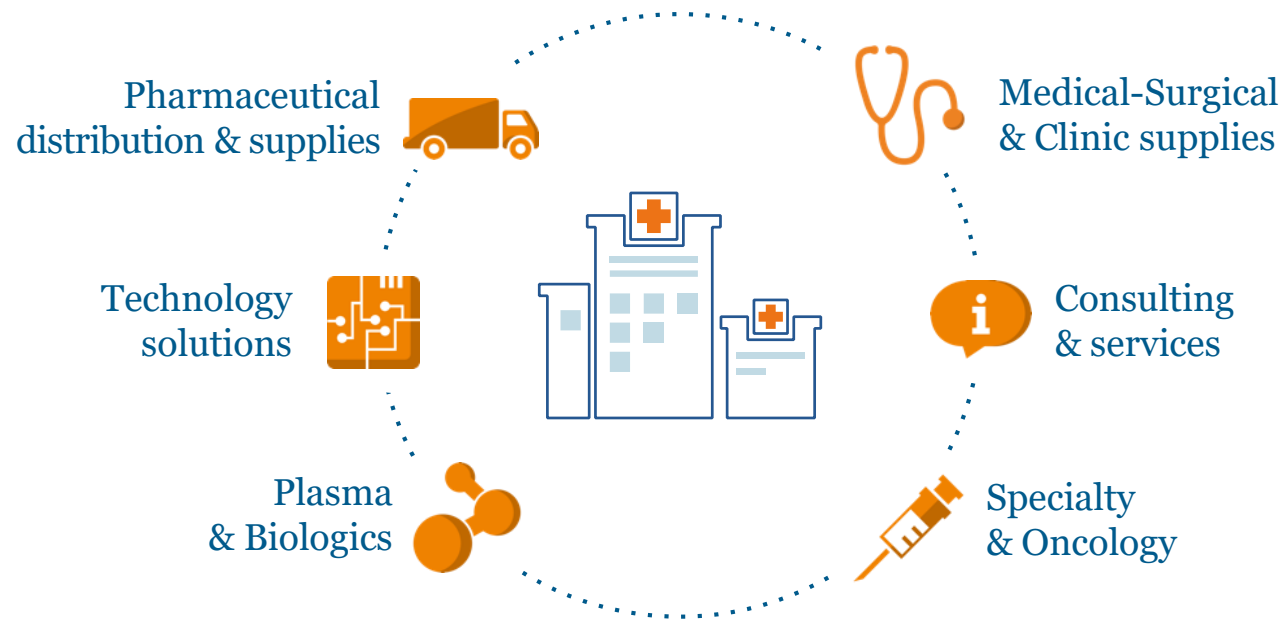
*“The **US Oncology Network** provides practice management resources that have helped us drive new development and achieve double-digit growth rates while continuing to thrive as an independent community oncology provider.”*

*Dr. R. Steven Paulson,
Practice President, Texas Oncology*

Health Systems

Delivering a healthy future

It's not an easy time for health systems. That's why we take a holistic approach to keeping them healthy. They surround the patient. We surround them.



It's About the Patient

*Sentara Healthcare **saved** nearly **\$2 million** in annual drug spend and **520 manual hours** with better drug spend intelligence.*

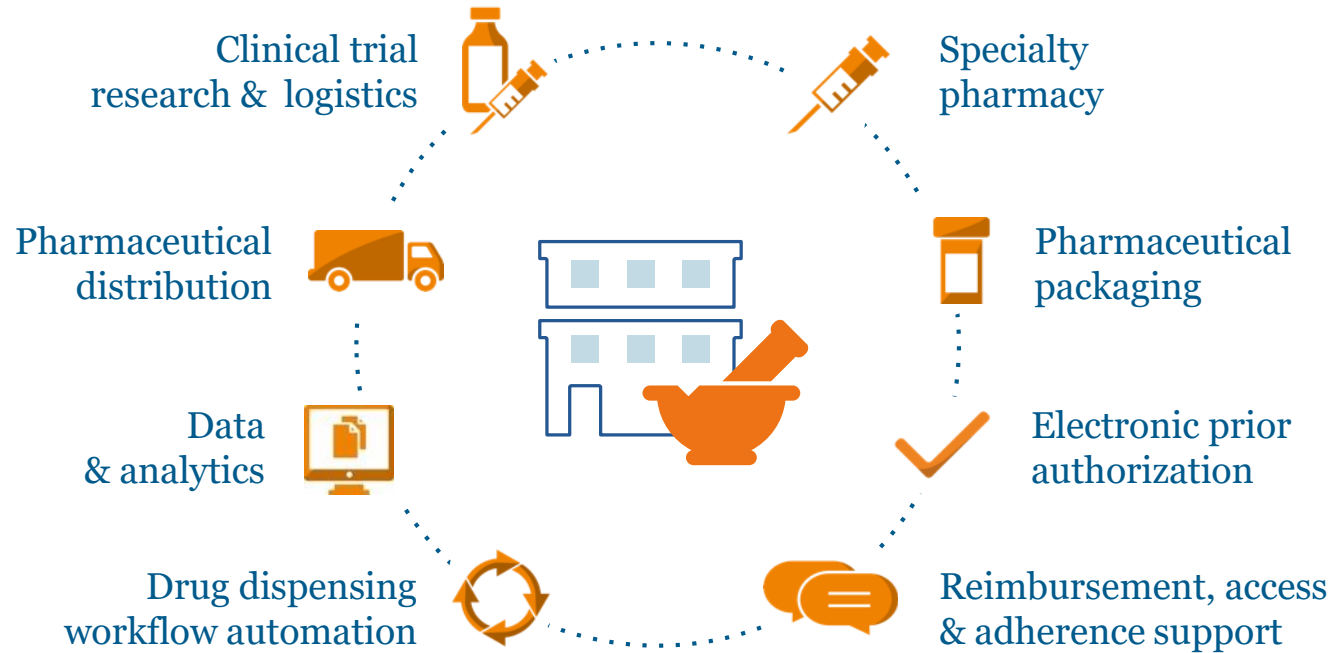


*That's more time and money for **patient care**.*

Manufacturers

Delivering access to improve lives

Extending and improving the quality of patients' lives is what drives manufacturers. Helping them realize their full potential is what drives us.



*Differentiated Partnership**

> 6M+ patients
receiving copay support

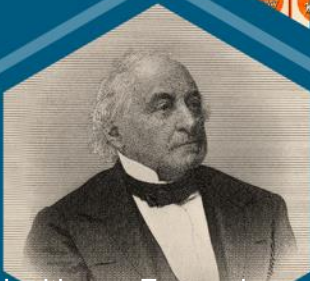
> 20M+ claims processed
to lower Rx costs

> 70,000+ patients supported
in **1,500+ clinical trials**

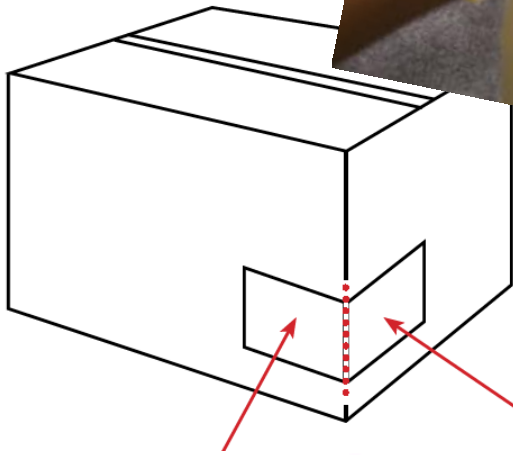
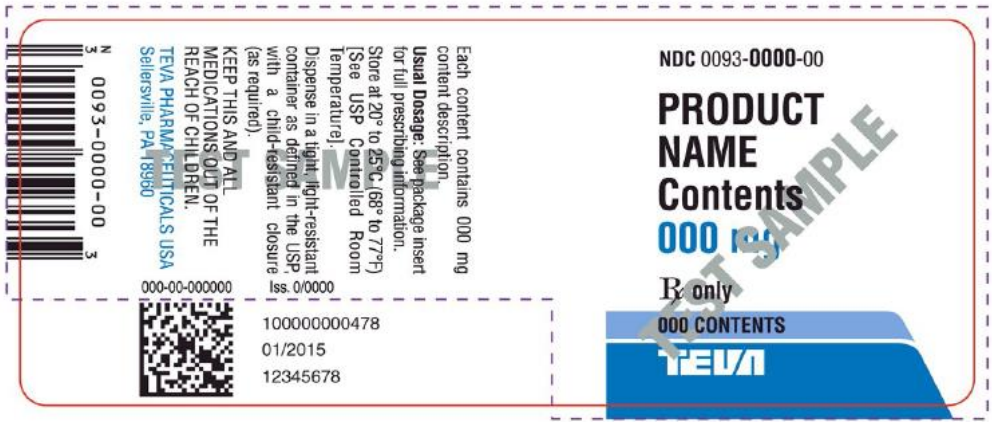


Pharmaceutical Distribution

 **McKESSON
PRODUCTS**



GS1 Bar Codes in Action



Internal vs. External Use

Proprietary Locations and Units

Shelf Locations
A-100-C-2

Tote Labels
T123456789



GS1 Locations and Units

GS1 GLNs

0010939144003

urn:epc:id:sgln:0010939.14400.0

GS1 SSCCs

(00)00109397371830085

GS1 SSCC Shipping Containers



Product Aggregation

Products aggregated to tote SSCC

Lots captured optionally at present

Serial numbers captured for later DSCSA requirements

Aggregation data being transmitted by EDI ASN now,
EPCIS in future



GS1 Standards in Electronic Communications

Incorporate GLN's, GTINs
and SSCCs into EDI

850 – Purchase Order (**S**,**C**)
855 – P O Acknowledge (**C**)
856 – Adv Ship Notice w/DSCSA (**S**,**C**)
810 – Invoice (**S**,**C**)
844 – Chargeback (**S**)
845 – Contract Load(**S**)
849 – Chargeback Response (**S**)
812 – Credit>Returns) (**S**,**C**)
832 – Item/Price Catalog (**C**)
820 – Remittance Advice (**C**)

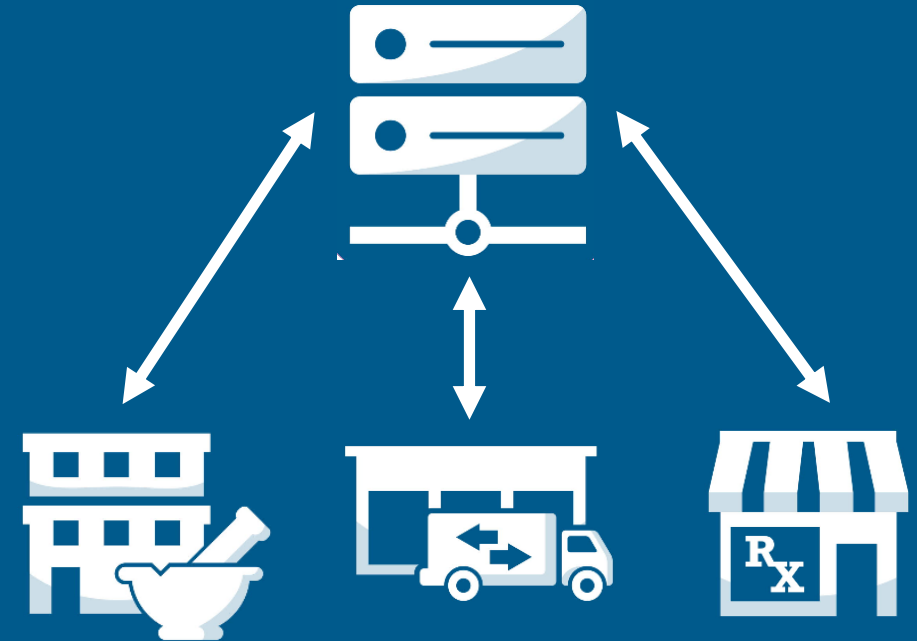
852 – Inventory Report (**S**)
867 – Sales Report (**S**)
879 – Item File (**C**)
888 – Cost File (**C**)
861 – Receipts Transaction (**C**)
875 – Grocery Purchase Order (**C**)
880 – Grocery Invoice (**C**)

(**S**) Used with Suppliers

(**C**) Used with Customers

Serialization Goal in the EU

- EU wide Central Repository to manage data to National Repositories
- Products uploaded to Central Repository and passed to National Repository where product is intended to be dispensed.
- In some cases, wholesale distributors verify a product against National Repository
- Dispensers verify against National Repository before dispensing AND report disposition when consumed



Product Marking in the EU

- Regarding the solutions it is including to read a 2D matrix code as per ISO IEC 16022 that include
 - GTIN code
 - Serial number
 - Expiry date
 - Batch number
 - when required a national number
- Most countries will use GTIN; some countries will use NTIN (e.g., Germany, France, Spain); both solutions are compatible with GS1 coding structure
- Others (e.g., Germany, Italy) will still require a national number



Serial Distribution in the EU

- Program in 15 steps has been agreed with all countries
 - setting of project team
 - construction of project plan
 - create a CAPEX/OPEX for FY2019
 - Process mapping of affected areas
- Completion of interfaces for serialization (Retail and Wholesale)
 - Modification of our pharmacy systems software
 - Modification of our warehouse management software
- Implementation of Wholesale solution by end of November 2018



Herba Chemosan Apotheker-AG; Pharma Belgium;
Belmedis; Tjellesen Max Jenne A/S; OCP France;
GEHE Pharma Handel; United Drug Distribution;
ADMENTA Italia; Brocef Norsk Medisinaldepot;
OCP Portugal; Kemofarmacija; AAH Pharmaceuticals



Sainsbury's gesundleben Careway Biologics
vitusapotek+ Pharmactiv **uniprix**
LloydsPharmacy

Returns Requirements in the US

- 1) Distributors must associate the original Transaction Information, Transaction History and Transactional Statement with a saleable return.
- 2) Verify that the product identifier affixed to the product corresponds with the data the manufacturer assigned.
 - A. Manufacturers can send serialized data for their shipments to their trading partners to be used for verification of future saleable returns
 - OR ---**
 - B. Manufacturers can make serial data available for query using a Verification Router Service requesting data for the distributors

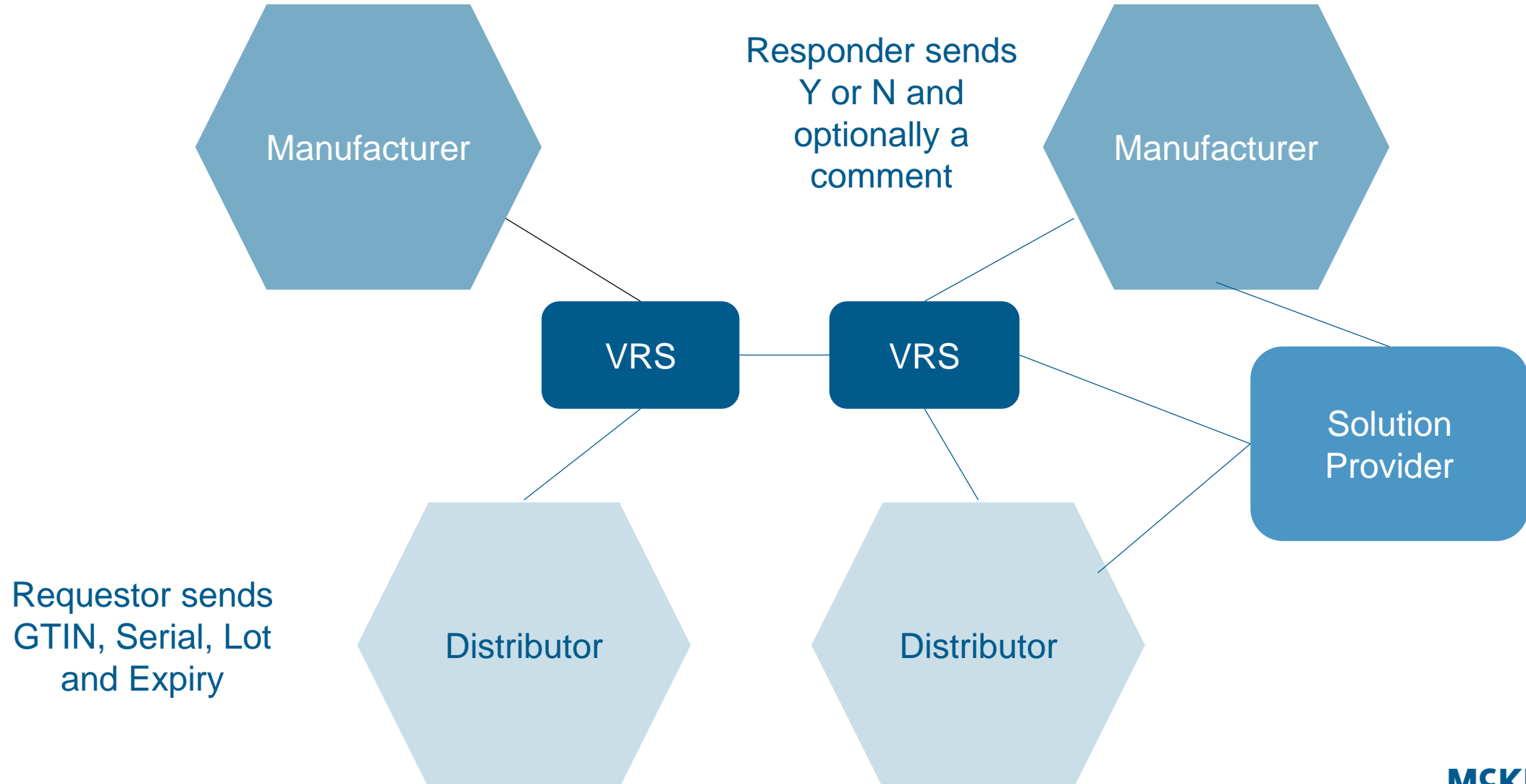


Annual saleable returns in US estimated at 60 million pieces across the industry



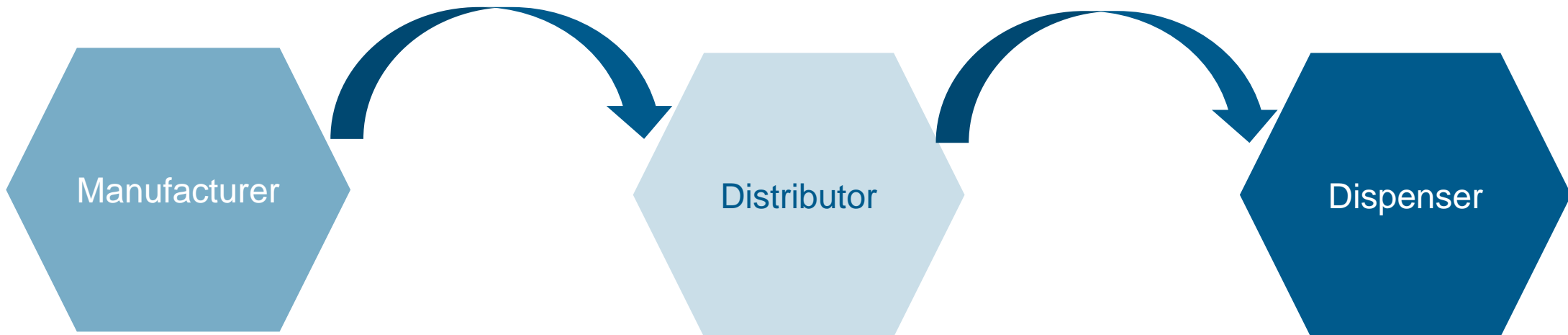
DSCSA Verification Router Service

Needed for 2019



DSCSA Serialized Data Exchange

Needed for 2023



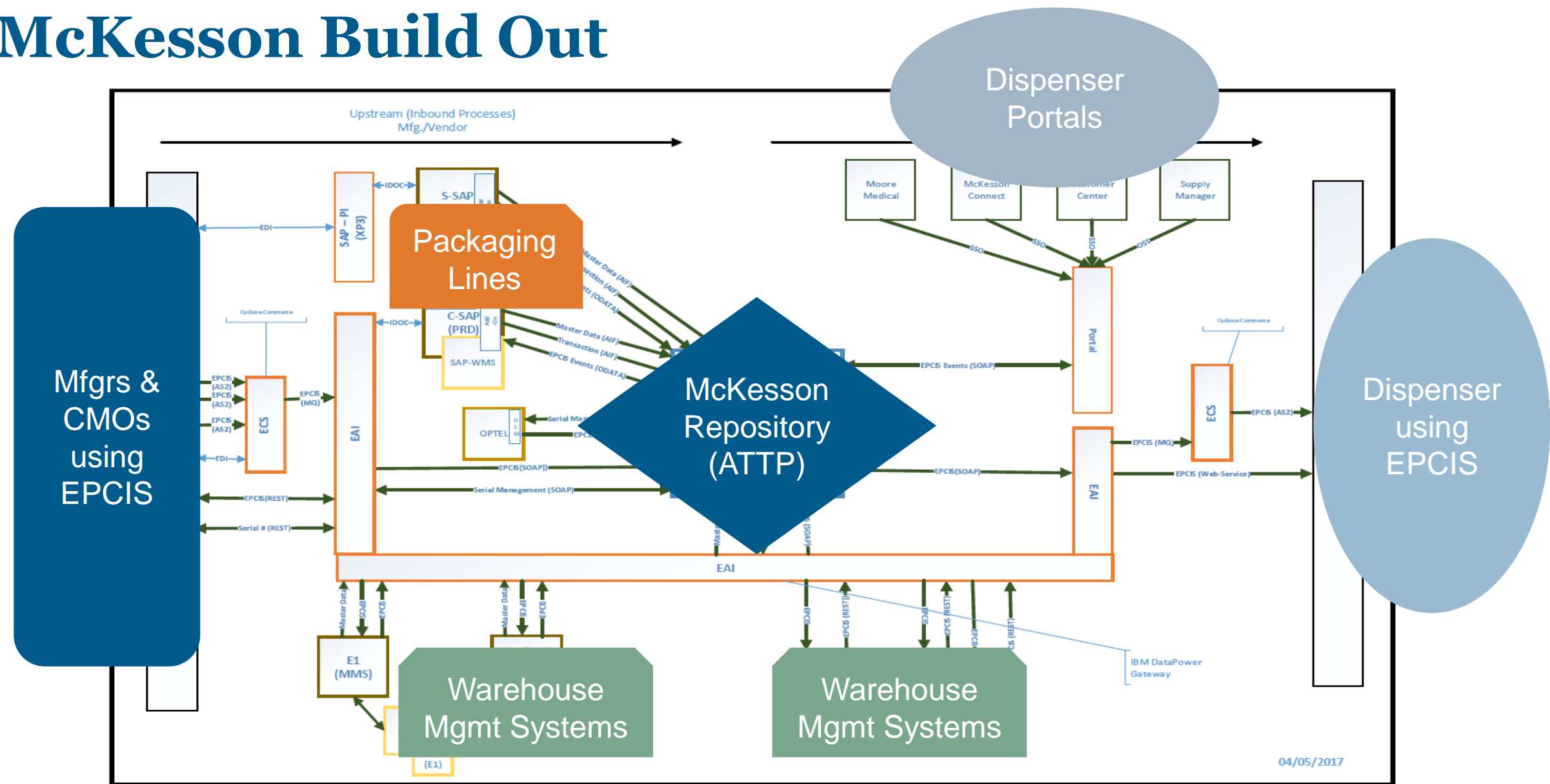
*Point to Point Connections using GS1 EPCIS
w/GTINs, GLNs and SSCCs*

Manufacturing and 3PL

- McKesson manufactures generic prescription and over the counter medicines along with medical surgical supplies in various countries around the world.
- We require the encoding with UPC-A or GS1 2D data Matrix barcodes.
- All are required to marked products with GS1 standard identifiers which may include GTIN, Lot, Expiry and Expiration.
- Production data such as serial numbers are communicated using EPCIS between McKesson and our contract manufacturer partners.
- McKesson provides 3PL logistics services to Brand Owners and utilizes the same GS1 Standards system above to coordinate with the Brand Owners CMOs.



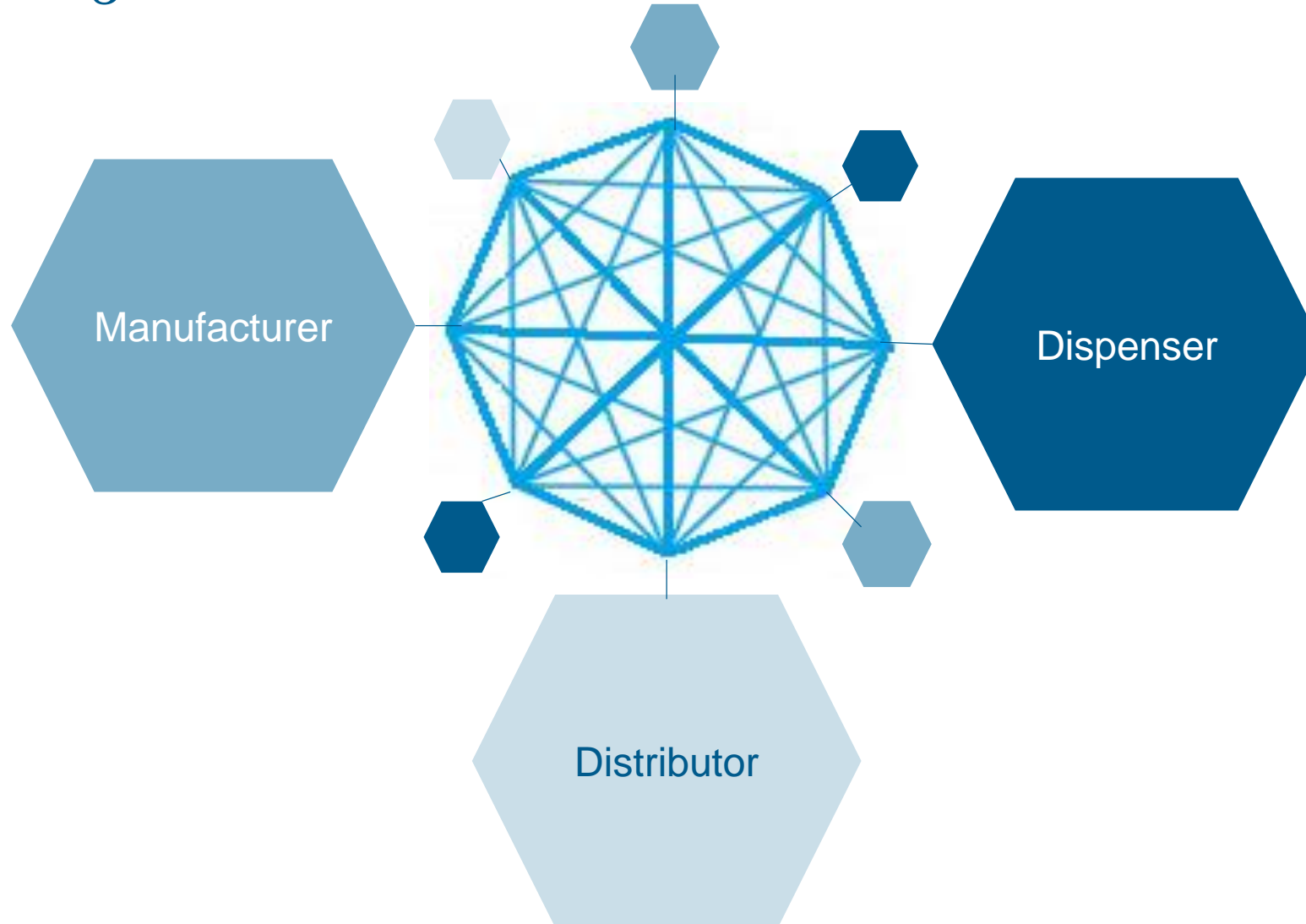
McKesson Build Out



04/05/2017

DSCSA Serialized Data Exchange w/ Blockchain

Possible for 2023



*Scott Mooney
Vice President, Distribution Operations
Supply Chain Assurance
McKesson Corporation
scott.mooney@mckesson.com
www.mckesson.com*



Questions from the audience!

Some closing thoughts



- Wholesalers, distributors and logistics providers rely on the use of GS1 standards
- Use of standards drives operational efficiency and accuracy in business operations
- We have a role to play ensure that *safer, more efficient care starts with a simple scan*, after all the product must be in the correct location when the patient needs it



Welcome Reception in Circo Restaurant



- **17:15 – 18:15**
- **MEET REMARKABLE PEOPLE**
- **AN AMAZING COLOMBIAN EXPERIENCE**





Enjoy the remainder
of the conference!