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
<table>
<thead>
<tr>
<th>Part</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part 1</td>
<td>ABC – Who Are We</td>
</tr>
<tr>
<td>Part 2</td>
<td>Importance of Interoperability</td>
</tr>
<tr>
<td>Part 3</td>
<td>Issues within current processes</td>
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<tr>
<td>Part 4</td>
<td>Removing the ambiguity and what “Will Be”</td>
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</tbody>
</table>
### 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

**Across Canada**
- 100+ specialty clinics
- Commercial 3PL facility
- Full commercialization services

**US**
- $1 billion invested over 10 years
- Full commercialization services

**Across Brazil**
- Specialty distribution to 3,500 clients
- Full commercialization services

**Globally**
- Crucial role in 15,900+ clinical trials

**EU**
- Market access services

**Across Australia**
- Commercial 3PL facility

**KEY GLOBAL OFFICE LOCATIONS (11)**
- OFFICE LOCATIONS (170+)
- NORTH AMERICAN DISTRIBUTION CENTERS (30+)
- DRUG STORAGE DEPOTS (14)
- SPECIALTY CLINICS (100+)
- SPECIALTY PHARMACIES (20)
- COMPOUNDING CENTERS (4)
- CALL CENTERS (8)
- ANIMAL HEALTH DISTRIBUTION CENTERS (30+)
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.
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

<table>
<thead>
<tr>
<th>DHL/NHS Supply Chain</th>
<th>How we work together</th>
<th>GS1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Sciences &amp; Healthcare Sector:</td>
<td>• 10+ years with GS1 Healthcare Sector Voting Member</td>
<td>• 111 member organizations</td>
</tr>
<tr>
<td>• 160 GxP facilities worldwide</td>
<td>• CEO John Gilbert on GS1 Board</td>
<td>• Member driven</td>
</tr>
<tr>
<td>• 21 GMP facilities worldwide</td>
<td>• Mike Meakin HLT</td>
<td>• 150 countries served</td>
</tr>
<tr>
<td>• 150+ DHL Pharmacists</td>
<td>• CEO NHS SC Nick Gerrard on UK Healthcare Advisory Board</td>
<td>• 20 different domains</td>
</tr>
<tr>
<td>• 44 Countries</td>
<td>• APAC CEO DGF Kelvin Leung on GS1 HK Board</td>
<td>• 2,500 people helping us</td>
</tr>
<tr>
<td>• Sub Sectors</td>
<td>• Member of Transport &amp; Logistics Sector</td>
<td>• Over 6bn transactions a day</td>
</tr>
<tr>
<td>– Biologics</td>
<td>• Using GS1 standards</td>
<td>• 38 HUG Countries</td>
</tr>
<tr>
<td>– Medical Devices</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DHL Supply Chain – Life Sciences & Healthcare GMP network

Geographical footprint

- Cold chain medical devices, e.g. diagnostics (2–8°C): CN, HK
- Controlled ambient: rest of the DHL Supply Chain LSH countries

Facilities: >170
Pallets: 2,107,000
Square meters: 2,026,000
Employees: >8,000
A global network of DHL facilities focused on Life Sciences & Healthcare

GS1 Standards for moving products through the Supply Chain | Bogota | 10 April 2018

STATUS 2018

Clinical Trials
Depots (DSC)

Life Sciences & Healthcare Warehouse (DSC)

Life Science Certified Station (2018)

Life Science Certified Station (plan 2018)
DHL Serialization journey

HUG Rome 2005

2004 Italy
Serialization solution (Bollini)

2006 DHL became GS1 member

2008–2012 Turkey
2D barcodes both printed & label application

2009 UK
Packaging & labeling to 27 EU countries in 16 different languages

2010 Singapore
Unit dose serialization service with 2D bar codes in

2013 The Netherlands
2D bar codes for France, Turkey, Greece, South Korea and Italy

2015 Brazil
Serialization pilots with 3 customers

End 2017-ongoing Global project

GS1 Standards for moving products through the Supply Chain | Bogota | 10 April 2018 24
Four specific serialization solutions identified, all of them have system implications

<table>
<thead>
<tr>
<th>Customer identified Solutions</th>
<th>Low/basic</th>
<th>Solution Comprehensiveness</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Tracking</td>
<td>No visibility to what or where serials are in the facility</td>
<td>Full visibility to what serials are in the facility</td>
<td>Full visibility to what and where serials are in the facility</td>
</tr>
<tr>
<td>EDI</td>
<td>Outbound only</td>
<td>Inbound/Outbound</td>
<td>Inbound/Outbound</td>
</tr>
<tr>
<td>Transactions</td>
<td>Order Confirmation</td>
<td>Smart ASN Receipt Confirmation Order Confirmation (pot. Inventory Adjust.)</td>
<td>Smart ASN Receipt Confirmation Order Confirmation Inventory Adjustment</td>
</tr>
<tr>
<td>Serial Number (S/N) capture</td>
<td>1 time capture</td>
<td>2–3 times capture &amp; validation</td>
<td>3+ times capture &amp; validation</td>
</tr>
<tr>
<td>Aggregation</td>
<td>Optional</td>
<td>Optional as VAS</td>
<td>Must have</td>
</tr>
</tbody>
</table>

Serial number tracking & validation
Example of site journey – Postponement capabilities in Nijmegen

1999

GMP license

2000

Redressing/delaying pricing & kitting

2001

Redressing & price labeling pharmaceuticals

2005

Labeling/Shelf life extension clinical trials redressing

2009

Start postponement

2012

Serialization

2013

Multiple markets

2015

Opening 2nd GMP area

2017

Procurement services and BOM mgmt.

ANVISA approved (August 2010, 157/10/ANVISA)

FDA approved (September 2010, FEI number 003324648)

IGZ (Dutch inspectorate, GDP and GMP, April 2015)

Nijmegen successful FDA Inspection
Postponement – Overview of key activities

Postponement activities

Transportation management

Product receipt/release

Storage in the multi-market hub

Manufacturing of final presentations & release

Distribution to customers

Key activities and quality control

Sub process

- BMR creation
- Printing labels
- Printing cartons
- Assembly
- Packing
- Blistering

- Serialization
- Specific labeling (EOF, Bollini)

Controls

- BMR approval
- Pre-print/pre-production checks
- In process control checks
- Line clearance
- Reconciliation
- QA checks
- Serial number registration
- QP certification

GS1 Standards for moving products through the Supply Chain | Bogota | 10 April 2018
The GS1 standards to ensure traceability and patient safety
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>DHL Supply Chain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mike Meakin</td>
<td>Vice President</td>
<td>Brindley House</td>
</tr>
<tr>
<td></td>
<td>Global Quality, Regulatory &amp; Compliance</td>
<td>Eastern Avenue</td>
</tr>
<tr>
<td></td>
<td>Life Science &amp; Healthcare</td>
<td>Burton on Trent</td>
</tr>
<tr>
<td>Phone</td>
<td>+44 (0) 1283 494211</td>
<td>DE13 0BB</td>
</tr>
<tr>
<td>Mobile</td>
<td>+44 (0) 7774 299402</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Fax</td>
<td>+44 (0) 1283 494237</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:mike.meakin@dhl.com">mike.meakin@dhl.com</a></td>
<td><a href="http://www.dhl.com">www.dhl.com</a></td>
</tr>
</tbody>
</table>
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

Consumers have more power

Value-Based Care is here and continues to prevail

Governments & regulators continue to rewrite the rulebook

Healthcare is changing rapidly

© McKesson Corporation 2018
We Make Better Health Possible

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 **$199B**¹

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 **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
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

* Fiscal year 2017 data.
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.

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.

It’s About the Patient
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

*McKesson Specialty Health Fiscal 2017 data.
Pharmaceutical Distribution
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
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
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
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

Requestor sends GTIN, Serial, Lot and Expiry

Responder sends Y or N and optionally a comment

Solution Provider

Manufacturer

VRS

VRS

Distributor

Distributor

Manufacturer

Moving Healthcare Forward © McKesson Corporation 2018
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.
DSCSA Serialized Data Exchange w/ Blockchain

Possible for 2023
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
Collaborate, network and learn

Enjoy the remainder of the conference!