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If anyone has concerns about the propriety of a discussion, please inform a GS1 US representative as soon as possible.

Please remember to make your own business decisions and that all GS1 standards are voluntary and not mandatory.

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Agenda

• GS1 System Overview ...............................................................GS1 US Healthcare Team
  - Who is GS1................................................................................Beth Gibson
  - GS1 Standards in Healthcare
  - Identify
  - Capture ......................................................................................Adrian Bailey
  - Share

• Healthcare Provider and GS1 Standards.........................Salil Joshi
110+ Member Organizations
Serving Business Around the World
The Global Language of Business

**GS1 Standards**

**Identify**
GS1 Identification Numbers
Companies, Products, Locations, Logistics, Assets, and Services

**Capture**
GS1 Data Carriers
Barcodes and EPC-enabled RFID

**Share**
GS1 Data Exchange
Master Data, Transactional Data, and Physical Event Data
In this presentation, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.
GS1 by the Numbers

- **2 million companies around the world** use GS1 Standards.
- **More than 5 billion GS1 barcodes** are scanned every day.
- **14.5 million products** are assigned U.P.C.s in the GS1 US Data Driver® tool.
- **Over 18 million products** are registered by brand owners in the GS1 Global Data Synchronization Network™ (GDSN®).

In this presentation, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.
GS1 Standards in Healthcare
GS1 Standards in Healthcare

Patient Safety

Healthcare Supply Chain Efficiency

- Automatic Data Capture
  - Barcodes
- Electronic Commerce
  - E-Records
  - E-Orders
  - E-Prescriptions
  - Order-to-Cash
- Inventory Visibility
  - Real-time Inventory
- Traceability
  - Product Tracking
  - Recalls
  - Asset and Equipment Tracking
- Compliance
  - FDA Unique Device Identification
  - FDA Drug Supply Chain Security Act

Standardized Data Exchange (GDSN/EDI/EPCIS)

Standardized Location Identification (GLN)

Standardized Product Identification (GTIN®)

Standardization → Interoperability
In this presentation, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.
GS1 Standards in Healthcare

- Together, we’re making it possible to follow drugs and medical devices from the manufacturer to the patient, improving efficiency, safety, and patient care.

  - Key benefits
    - Improving patient safety
    - Lowering costs through increased efficiency
    - Reducing medication errors
    - Enabling supply chain visibility
    - Facilitating effective product recalls
    - Tracking of pharmaceutical products/medical devices
    - Reducing introduction of counterfeit products
    - Enhancing inventory management
    - Linking critical product data to the patient record
    - Supporting regulatory compliance
    - Optimizing order, invoice, sales reporting, and chargeback/rebate processes
IDENTIFY

GS1 Identification Standards in Healthcare
## What is a GTIN?

<table>
<thead>
<tr>
<th><strong>Global Trade Item Number</strong></th>
<th>• An identification number of the GS1 System, therefore unique and unambiguous</th>
</tr>
</thead>
</table>
| **Globally Unique Number**  | • 8, 12, 13, or 14 Digits  
 | \hspace{1cm} • Identifies Products or Services                     |
| **A Global Standard**       | • For Collaborative Commerce                                     |
Global Trade Item Number (GTIN)

A number that uniquely identifies trade items. GTINs are encountered most frequently at retail point of sale and on inner packs, cases, and pallets of products in a distribution center/warehouse.

8, 12, 13 or 14-Digit Numerical Number

GTIN-12

GTIN-14
Healthcare Model
GTIN® plus Secondary Information

• GTIN – Global Trade Item Number®
• Expiry Date
• Lot Number
• Serial Number
What is a Global Location Number (GLN)?

- A GS1 System standard for collaborative commerce
- Always a unique 13-digit number that identifies:
  - Legal entities
  - Functional entities
  - Physical locations
- May also be encoded within a barcode for specific business applications and placed on shipping labels
  - “Ship to – Deliver to” locations
  - “Bill to – Invoice to” locations
  - “Purchased from” locations
  - Shelf locations
Global Location Number (GLN)

Used to identify physical and functional locations as well as legal entities. GLNs are used to identify parties to business transactions; functional groups within a company; or real, physical “places” that might ship, receive, process, or hold inventories.

13-DIGIT NUMERICAL NUMBER

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₁ N₂ N₃ N₄ N₅ N₆ N₇ N₈</td>
<td>N₉ N₁₀ N₁₁ N₁₂</td>
<td>N₁₃</td>
</tr>
</tbody>
</table>
GLN Structure Example

<table>
<thead>
<tr>
<th>Location</th>
<th>GS1 Company Prefix</th>
<th>Location Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate Entity</td>
<td>0312345</td>
<td>00000</td>
<td>4</td>
</tr>
<tr>
<td>Corporate Headquarters Building</td>
<td>0312345</td>
<td>00001</td>
<td>1</td>
</tr>
<tr>
<td>Philadelphia Factory</td>
<td>0312345</td>
<td>00002</td>
<td>8</td>
</tr>
<tr>
<td>Cherry Hill Factory</td>
<td>0312345</td>
<td>00003</td>
<td>5</td>
</tr>
<tr>
<td>Willow Grove Sales Office</td>
<td>0312345</td>
<td>00004</td>
<td>2</td>
</tr>
<tr>
<td>Philadelphia Distribution Center</td>
<td>0312345</td>
<td>00005</td>
<td>9</td>
</tr>
</tbody>
</table>

Click here to access the Check Digit Calculator
GLN Hierarchy Example

- Corporate GLN
- Bill to GLN A
  - Ship to GLN A1
  - Ship to GLN A2
    - Deliver to GLN A2a
    - Deliver to GLN A2b
- Bill to GLN B
  - Ship to GLN B
- Paid-by location
  - Ship to GLN C1
  - Ship to GLN C2
    - Deliver to GLN C2a
    - Deliver to GLN C2b
    - Deliver to GLN C2c
    - Deliver to GLN C2d
  - Ship to GLN C3
    - Deliver to GLN C3a
    - Deliver to GLN C3b
  - Ship to GLN C4
    - Deliver to GLN C4a
    - Deliver to GLN C4b
    - Deliver to GLN C4c
- Bill to/ Ship to GLN D

Key

- Level 1
- Level 2
- Level 3
- Level 4
Serial Shipping Container Code (SSCC)

• A globally unique 18-digit number that identifies a specific logistics unit of products:
  - e.g. pallets, air cargo containers, returnable totes, boxes for parcel delivery, etc.
• Used as a reference number (license plate) only
• Used inside Advance Ship Notice (ASN, EDI 856)
• A global standard within the GS1 System
• An ISO standard for transport labels worldwide
• Reuse of SSCC is 1 year

• Do not confuse with Global Trade Item Number® (GTIN®)
Serial Shipping Container Code (SSCC)

- Used for an item of any composition established for transport and/or storage which needs to be managed through the supply chain.
- The SSCC should be used in the Advance Shipping Notice (ASN).

18-DIGIT NUMERICAL NUMBER

<table>
<thead>
<tr>
<th>Application Identifier</th>
<th>Extension Digit</th>
<th>GS1 Company Prefix</th>
<th>Serial Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>N1</td>
<td>N2 N3 N4 N5 N6 N7 N8 N9 N10 N11 N12 N13 N14 N15 N16 N17 N18</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(00) 106141410759497498
CAPTURE

GS1 Data Carriers in Healthcare
GS1 Data Carriers

- EAN/UPC (Used for many Class I and some Class II Healthcare)
- ITF-14
- GS1-128 (Used for Class III and Class II Healthcare)
- GS1 DataBar
- GS1 DataBar with Composite Component
- GS1 DataMatrix (Used for Class III and Class II Healthcare)
- EPC-enabled RFID

* Barcodes not to scale.

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Features of EAN/UPC

- Encodes only the Global Trade Item Number® (GTIN®)
  - GTIN-12, GTIN-13, or GTIN-8
- Point-of-Sale (POS) scanning
  - POS scanners are optimized for EAN/UPC
- Omni-directionally readable
- Enables fast and accurate tracking of retail consumer trade items in the supply chain
USAGE of EAN/UPC

- Used on standard trade items to uniquely identify products in the food, healthcare (OTC), consumer products, apparel, electronics, and hardlines industries.

- Used for trade items crossing POS

- Items marked are typically intended to be scanned at retail point-of-sale (POS), but this symbology is allowed for general distribution scanning when magnified to between 150-200% of the nominal size.
Features of GS1-128

- Encodes *all* of the GS1 Identification Keys and all additional GS1 Application Identifiers (AI) up to 48 characters
- Allows for “concatenation” of data strings
- “All the info in one scan”
- Enables fast and accurate tracking of non-consumer trade items and other specific data in the supply chain
Usage of GS1-128

• Used on standard trade items, locations, logistic units, and assets in the supply chain

• Uniquely identifies trade items or assets in cartons, inner packs, cases, pallets or locations

• Through the use of AIs, it can be used to share batch/lot number, serial number, expiration and best before dates, physical locations and entities, etc.

• GS1-128 is *not* intended to be scanned at retail point-of-sale (POS)
Features of GS1 DataMatrix

- Encodes all of the GS1 Identification Keys and all of the GS1 AIs
- Carries up to 2,335 characters in a very small “footprint”
- Can be directly marked on parts (DPM) — does not need a label. For example, laser etching.
- Has considerable “error correction”— the barcode can be partially destroyed and still deliver the data
- Enables fast and accurate tracking of non-consumer trade items and other specific data in the supply chain
- Ability to track additional information using over 100 different GS1 AIs to meet specific requirements, such as parts for the US DoD
- Holds large amounts of data in a relatively small space and utilizes a built-in error correction to ensure scan ability, even to a damaged symbol
Usage of GS1 DataMatrix

- Used on standard trade items and assets in the supply chain, primarily the Healthcare and Aerospace & Defense industries

- Uniquely identifies very small Healthcare items, parts, components, office equipment, etc.

- Through the use of AIs, they can be used to share batch/lot number, serial number, expiration and best before dates, etc.

- Items marked are NOT intended to be scanned at retail point-of-sale (POS)
SHARE

GS1 Data Sharing Standards in Healthcare
The GS1 Global Data Synchronisation Network® (GDSN®) is a network of interoperable data pools enabling collaborating users to securely synchronise master data based on GS1 standards. GDSN supports accurate, real-time data sharing and trade item updates among subscribed trading partners.

https://www.gs1.org/how-gdsn-works
GDSN® Basics

- Product information is
  - Loaded/supplied by Seller
    - Can be Labeler, Distributor, GPO, any party selling the item
  - Multiple messages can exist for each instance of GTIN®, Seller (Information Provider), and Target Market
    - One message can be used for multiple target markets
  - Can include UDI Database information
    - FDA and Other databases can be fed from the Labeler’s GDSN Data Pool

- Data Retrieval is accomplished
  - By Publication-Subscription matching
    - Upon each change and on processing cycle of Buyer (Recipient)
    - For each hierarchy

- Contains information about any item
  - Medical Device, Pharmaceuticals, Office Supplies, Food, Janitorials, Textiles, Others
Data synchronization is the electronic transfer of standardized product and entity information between trading partners and the continuous synchronization of that data over time.
Data Flow via GDSN®

The **GS1 Global Registry®** is a single repository where basic data is registered. The GS1 Global Registry identifies the data pool location of source data.

**Data Pools** provide data that is standards conformant, and interoperable in the GDSN®. The data pool performs the transactions of sending and receiving validated product information between partners inside or outside the data pool.

**Select one data pool as a SINGLE point of entry to the GDSN**

- **Step 1**: Load Data
- **Step 2**: Register
- **Step 3**: Subscription
- **Step 4**: Publish Data
- **Step 5**: Recipient Confirmation

**3rd Party Government Database Loading**: The FDA utilizes the HL7 SPL message to receive machine to machine feeds of product information. To accomplish this, the source data pool can act as a 3rd Party Provider of data on behalf of a Data Supplier. Data confirmation messages will be returned to the Source Data Pool. The Source Data Pool will communicate these return messages to the Data Supplier.
Electronic Product Code Information Services (EPCIS)

EPCIS is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers. It helps answer the “what, where, when and why” questions to meet consumer and regulatory demands for accurate and detailed product information.

https://www.gs1.org/epcis
EPCIS Visibility Data Content

- Visibility data consists of **events**, each of which records something that happened in the real world.
- Often, though not necessarily, triggered by reading an RFID tag.
- An event has four dimensions:
  - **What**: what physical objects were involved (EPC)
  - **When**: when the event took place (timestamp)
  - **Where**: where the event took place (location identifier)
  - **Why**: what business process step was being carried out

Where and Why are what distinguish EPCIS visibility data useful to a business application from raw RFID or Bar Code data.
Healthcare Providers and GS1 Standards
Meeting Provider Challenges with GS1 Standards

• **Regulation Compliance and Risk Management**
  - Recall process is difficult to optimize
  - Medical device regulations
  - Pharmaceutical regulations

• **Operational Efficiency**
  - Cash flow issues
  - Inaccurate pricing
  - Monitoring expiration dates of inventory
  - Difficulty in capturing patient charges
  - Need to re-label products
  - Difficulty in asset and instrument tracking

• **Safety and Quality of Care**
  - Preventable errors
  - Non-value added tasks
  - Getting the right product to the right patient
  - Managing Electronic Health Records (EHRs)
  - Manual records and requests
Meeting Provider Challenges with GS1 Standards

The vision of healthcare providers is to be data-driven organizations that harness the power of data throughout their organization. By using UDI throughout health IT systems, hospitals can fuel operational efficiencies and process improvements. UDI can translate to significant advances in delivery of care, patient safety, and cost reduction.
GS1 Standards in Healthcare

- **GS1 Healthcare Reference Book 2016-2017: Stories of successful implementations of GS1 standards**
  - 15 Stories from around the globe describing use of GS1 standards in various healthcare settings
GS1 Healthcare Industry Initiatives
GS1 Healthcare - an expanding, committed community of globally engaged stakeholders...
...and leading healthcare providers and government agencies
Join the GS1 Healthcare Global Public Policy Team

- **Teleconferences** every two weeks and **open face-to-face sessions** twice this week on Tuesday (Pharmaceuticals) and Wednesday (Medical Devices)

- All documents online in **GS1 HCPP Community room and DataBase**
  - Registration necessary
  - Access only for GS1 MOs and GS1 Healthcare members

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**Open only to global members of GS1 Healthcare**

To Join visit: [https://www.gs1.org/healthcare/membership](https://www.gs1.org/healthcare/membership)
GS1 US Workgroups

**EDI Implementation Workgroup:** Supports development of a common healthcare industry approach for implementing Electronic Data Interchange (EDI) using GS1 Standards

**Provider Advisory Workgroup:** Provides a forum for healthcare provider member organizations to collaborate

**Price Accuracy Initiative Workgroup:** Supports the use of the Global Location Number (GLN) in the medical device chargeback process, customer identification and best practices using the GLN to improve pricing accuracy between stakeholders

**Rx Secure Supply Chain Workgroup:** Supports pharmaceutical supply chain members in their efforts to use GS1 Standards for business and regulatory purposes requirements in the Drug Supply Chain Security Act (DSCSA)

**GDSN Vital Attributes:** Supports the development of the product attributes in GDSN that are required to drive interoperability of key business processes between trading partners.
Questions?