



1WorldSync Healthcare Webinar

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November 5, 2014

CONNECTING TRUSTED PRODUCT DATA EVERYWHERE

Agenda

- Shifting Healthcare Landscape
 - Industry Groups (HTG, CHeS) & GS1 Standards
 - Regulatory Compliance
- GS1 Standards Overview
 - GDSN Overview
 - 1WorldSync Role
- Improving patient safety, supply chain efficiencies and regulatory compliance through product information exchange



Healthcare Industry Overview



Healthcare

- Healthcare Transformation Group (HTG) and Coalition for Healthcare eStandards (CHeS) – Utilization of GS1 Standards
 - Driving the use of GS1 Standards across the HC Industry
- Provider Engagements
 - Direct GDSN engagements, similar to Operators in FS Industry
- Regulations: UDI, DSCSA, & Meaningful Use
 - Driving HC industry across the product categories
- Industry Adoption
 - Global adoption due to regulation



Coalition For Healthcare eStandards (CHeS)

- Focused group associated with the Healthcare Supply Chain Association (HSCA)
- Ongoing focus on promoting standards for healthcare eCommerce
- Recent focus on GS1 standards and UDI ways to accelerate adoption and increase quality of data
- Strong participation from major GPOs Amerinet,
 Premier, MedAssets, and Novation
- Undertook initiative to "normalize" required attribute elements among major GPOs to reduce barriers



CHeS GTIN Adoption Initiative

- Recognition that variation in requirements from major GPO partners could be an obstacle to manufacturers implementation of standards.
- Voiced strong support for GS1 standards as the basis of UDI standards.
- Undertook initiative to "normalize" required attribute elements among major GPOs to reduce barriers
- Developed document to define these required attributes and process to promote with manufacturers
- Proposal for case study with GPO/Manufacturers



CHeS Landing Page



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Coalition for HC eStandards



GDSN

Communications



Key Documents

- CHeS Minimum Product
 Attributes List
- Next Level GDSN Attribute Information
- HSCA "Total Visibility" Press Release

GDSN® Initiative

The Healthcare Supply Chain Association (HSCA) and its group purchasing organization (GPO) members are leading the way on improving the accuracy and accessibility of product information available to the supply chain. To that end, the HSCA has created a focused group to promote standards for healthcare eCommerce called the Coalition for Healthcare eStandards (CHeS).

CHeS has developed the "Total Visibility Project," an industry best practice related to data synchronization that supports greater efficiency in the healthcare supply chain while also improving patient safety. This initiative will create greater transparency and access to accurate product information for providers, at both the procurement and clinical level, ensuring that the right product gets to the right patient at the right time. Please click the press release linked in the left navigation to learn more.

To provide healthcare trading partners access to your product information, the GPO members of HSCA are engaging in data synchronization through the Global Data Synchronization NetworkTM (GDSN). GDSN is an automated, standards-based global environment for the electronic transfer of standardized product information between trading partners. GDSN helps



Updated Implementation Guides



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HOW WE CAN HELP CUSTOMER RESOURCES ABOUT 1WORLDSYNC

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Amerinet



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GDSN

Communications

- Amerinet Letter to Suppliers
- Amerinet Partners with 1WorldSync for Access to

Key Documents

- Amerinet Trading Partner
- New Amerinet Implementation Guide

GDSN® Initiative

As a leading national healthcare gre with acute and alternate care proviclinics, and doctor offices-to create improvement resources, guidance, and utilization, new financial tools revenue, and champion quality, Ar communities they serve.

Amerinet is a member of the GDSN implementing these standards with of the supply chain. Amerinet ador

Premier



GDSN Communication

Premier Letter to Suppliers

Key Documents

- Premier Trading Partner
- Premier Implementation

Education

GDSN® Initiative

Premier adopted The Global Data Synchronization Network™ (GDSN®) in 2009 and since then has been helping its approximately 3,000 hospital and 110,000 other providers to further enhance patient safety and reduce costs in the healthcare industry sector. Premier was the first GPO to announce its endorsement of GS1® supply chain standards, and was also the first to expect its manufacturers to comply with this important initiative. Use of the standards allows supply chain stakeholders to definitively identify all items purchased by healthcare providers and efficiently exchange and update this information.

All partners in the healthcare supply chain need to be aware of this industry-wide initiative and understand the benefits of using one common global data standard. The Healthcare Tool Kit (listed on the right navigation bar) supports these industry sunrise goals and provides what you need to know to get started with GS1 Standards today.

You can access the Healthcare Supplier Tool Kit at www.gs1us.org/hcsuptoolkit.

< BACK TO CUSTOMERS



AHRMM Takeaways

- Annual Association for Healthcare Resource and Materials Management (AHRMM) Conference August 3-6, 2014
- Premise: The Healthcare Industry is well on its way to realizing the benefits of GS1 Standards and eventually, the GDSN.
- <u>Theme</u>: The Healthcare Industry can leverage the successes of other Industries, such as Retail and Foodservice, in achieving supply chain efficiencies.
- <u>Conclusion</u>: The Healthcare Industry, as a whole, needs to adopt a single set of standards.
- Recommendations:
 - 1. Look at Walmart adoption of GS1 Standards as a model to follow
 - 2. Change the Healthcare Industry view of "patients" to "customers" and "consumers"

This shift in viewing the patient as a consumer will have a profound effect on healthcare. The industry is seeking to provide greater visibility to end consumers, in terms of what products are provided and used on them, as well as creating a better and more streamlined reporting.



GS1 Healthcare US and FDA's UDI & GUIDID

- GS1 Healthcare US continues to educate and support companies new to the GS1 standards
- Aligned with GS1 Global office for the Issuing Agency status
- UDI & GUDID Update
 - First Compliance Date Sept 24, 2014
 - Almost 32,000 DI records submitted to GUDID with approx. 220 labelers (as of 1st compliance date)
 - Downloads from GUDID expected towards end of year
- Increasing interest in "regulated healthcare that is OTC"
- GS1 Healthcare US continues to meet with FDA on a monthly basis
- Attended UDI Conference (led by FDA)
 - Baltimore, MD
 - October 28-29, 2014





FDA Unique Device Identification Rule

MARK

- Label with AIDC (barcode)
- UDI (device identifier) + PI (product identifier)
- PI = GTIN

SUBMIT

- Publish UDI plus required data attributes to Global UDI Database (GUDID)
- GDSN is one mechanism to publish that data once to both the FDA and customers

COMPLY

Year 1 (2014): Class III and devices licensed under PHS Act

Year 2 (2015): Class II/I implants and life-supporting/sustaining

Year 3 (2016): Remainder of Class II

Year 4 (2018): Class I

* For direct marking: Compliance dates are extended by 2 years except for FDASIA implants and life-supporting/sustaining



UDI Final Rule posted to Federal Register September 24, 2013

FDA UDI Website: www.fda.gov/gov and click on "UDI Helpdesk"

DSCSA – Drug Supply Chain Security Act Traceability in the Drug Quality and Security Act (DQSA)

JAN 2015



NOV 2017



NOV 2023

- Transaction Statement*
- Capture Lot Level
 Traceability and
 Verification of Suspect or Illegitimate
- By JULY 2015 for dispensers

Product

- Identifier Package and
 Homogenous
 Case
- Mark Product ID as SNI with Lot # and Expiry Date in a 2D Data Matrix Barcode
- **Distribute** by NOV 2019
- Dispense by NOV 2020

- Capture Item Level Traceability
- Sunset Lot Level Traceability

Transaction Information

- Product Name
- Strength, Dosage Form
- NDC
- Container Size
- Number of Containers
- Lot #
- Date of Transaction, Date of shipment if applies
- Business Names of Transacting Parties



*Refers to the Rule of data storage requirements, exceptions (direct ship, drop, ship, returns, 3rd party solutions, 3PLs, repackagers, effect on State laws) FDA Draft Guidance will outline standards for Transaction Statement Information and History SNI = Standardized Numerical Identifier – will require sunset of the 2004 FDA Bar Code Rule DQSA (H.R. 3204) November 27, 2013 http://www.fda.gov/Drugs/Drug

GS1 Standards



GS1 Standards in Healthcare



IDENTIFY GS1 IDENTIFICATION NUMBERS

GLN Global Location Number GTIN® Global Trade Item Number® **SSCC** Serial Shipping Container Code **EPC***/SGTIN Serialized Global Trade Item Number

GLN GTIN GTIN SSCC GLN SSCC GLN GTIN GTIN GLN SSCC SSCC MANUFACTURER ITEM CASE PALLET TRANSPORT DISTRIBUTOR/ DISTRIBUTION ITEM TRANSPORT PALLET TRANSPORT CASE HEALTHCARE PATIENT WHOLESALER CENTER PROVIDER

CAPTURE GS1 DATA CARRIERS

EPC-ENABLED RFID BARCODES

EAN/UPC



GS1-128



ITF-14



GS1 DataBar®



GS1 DataMatrix



HF RFID

UHF RFID



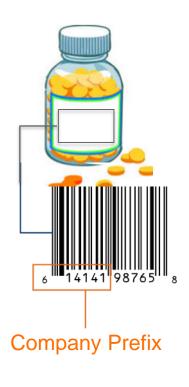
SHARE GS1 DATA EXCHANGE

PRODUCT MASTER DATA GLN Registry, Global Data Synchronization Network (GDSN*) TRANSACTIONAL DATA Electronic Data Interchange (EDI) PHYSICAL EVENT DATA EPC Information Services (EPCIS)





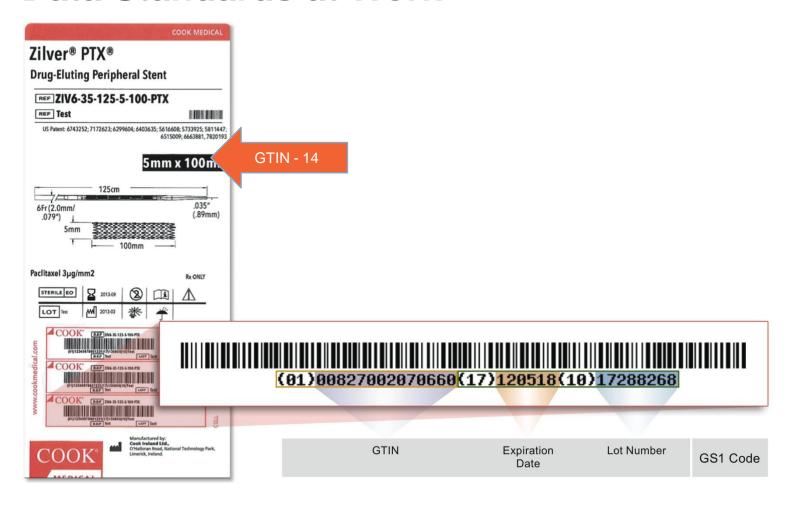
The Foundation: GS1 Company Prefix



- Assigned to the Brand Owner
- Used to create globally-unique identification numbers for:
 - Products (GTIN)
 - Inner Packs, Cases, and Pallets (GTIN)
 - Locations (GLN)
 - Assets
 - Services



Data Standards at Work

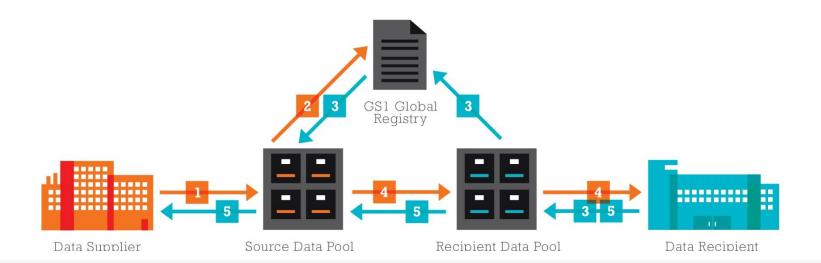




GDSN Overview



Global Data Synchronization Network (GDSN)



How the GDSN Works

The GDSN allows trading partners to synchronize standard product and location information with each other in five steps:

- 1 LOAD DATA
 - The data owner registers product and company information.
- 2 REGISTER DATA
 - A small subset of this data is sent to the GS1 Global Registry.
- 3 REQUEST SUBSCRIPTION

The data recipient, through its own data pool, subscribes to receive a seller's information.

- 4 PUBLISH DATA
 - The source data pool publishes the requested information to the recipient's data pool.
- 5 CONFIRM & INFORM

The data recipient sends a confirmation to the data owner via each company's data pool, which informs the supplier of the action taken by the retailer using the information.

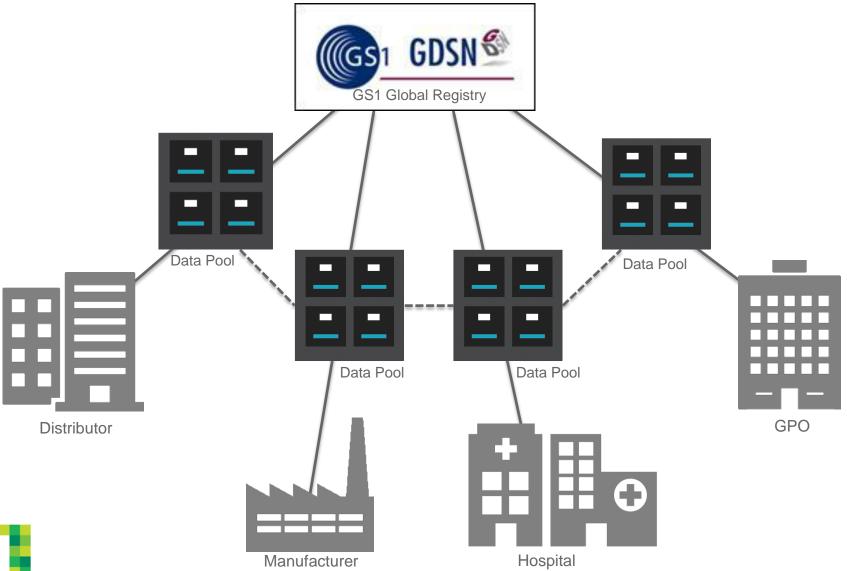


Benefits of GDSN Engagement

- Single source of product information
 - Allows for one pipe of information
 - Supplier owns data
 - Information is updated as the supplier makes updated
- Utilization of a unique global product identifier (GTIN)
 - Ensures what you order, is what the Supplier ships
 - Establishes ability to have product information tied to traceability by storing all ordered item numbers tied to Supplier numbers
- Data Quality becomes opportunity
 - Allows the ability to truly receive ROI from Data Quality on:
 - Nutritional
 - Allergen
 - Case/Weight/Cube



GDSN Healthcare Visual





1WorldSync Data Synchronization Steps



Supplier /
Manufacturer
(Data Source)



Item Management



Uniquely identified by 14-digit "Global Trade Item Number"



Advantages of Using GDSN in Healthcare

- Reliable Data
- Quality Data
- Current Data
- Ease of Use
- One Collaborative Network

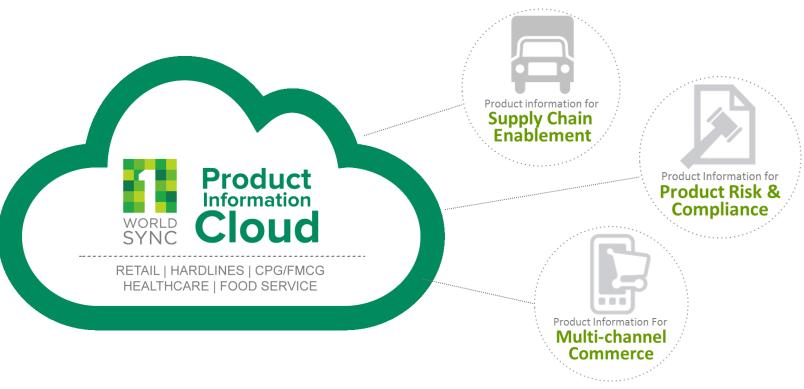


1WorldSync Overview



Our Solution

SOLUTIONS



A trusted product information network for global manufacturers and brand owners, to sync and exchange trusted product data and content with customers, distributors and authorized 3rd parties.



Relationship with GS1



GS1 US and Germany

- Global Standardization
- Global Data Synchronization Network (GDSN)
- Community Management



CONNECTING TRUSTED PRODUCT DATA EVERYWHERE



1WorldSync

- Product Data Synchronization
- Price Data Synchronization
- Regulation & Sustainability Data Management
- Coupon Management
- Consultancy



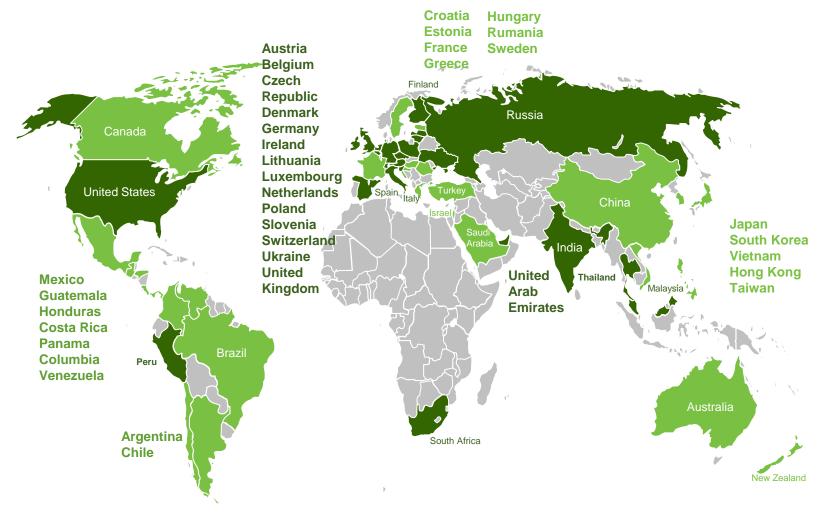
1WorldSync's Footprint

We are the trusted, global source of authentic, enriched data to facilitate management of B2B and B2B2C product information more efficiently and completely.

- We help more than 15,000 companies in over 50 countries
- Partner with 19 GS1 Member Organizations Globally
- Represent over 11 million items in the Global Data Synchronization Network "GDSN"
 - ~ 81% of entire GDSN 12,200,000 registered items
- We work alongside GS1, leading industry initiatives in Apparel General Merchandise, CPG/Grocery, Foodservice, Fresh Foods, and Healthcare



1WorldSync Global Reach, Local Connection 54 Countries





- 1WorldSync Customer Locations (29)
- 1WorldSync Data Pool Platform Technology
 - + Customer Locations (25)

Using an Industry Focused Strategy

1WorldSync strategically focuses on 4 key industries:









- Our main goal is adoption of the GDSN and improvement of product data management processes throughout the global supply chain
- Industry Engagement, Professional Services, Implementation Services, Customer Support and Technology functions follow specific requirements from these industries



How Data Pools Help Recipients of Data

- 1WorldSync provides:
 - Education and Training
 - Technical Support
 - Attribute Review
 - Pulling in Data
 - Internal Business Process Design
 - Internal, Customized Validations
 - Downstream Process Flow
 - Catalogue Item Confirmation (CIC) Design



How Data Pools Help Suppliers

- 1WorldSync provides:
 - Education and Training
 - Technical Support
 - Healthcare Attribute Review / Gap Analysis
 - Data Integrity, Standards and Validations
 - Done at various stages of Item Lifecycle
 - Upload Capability
 - Adding, Linking and Publishing Items via GDSN
 - Reporting and Internal Business Process Design
 - Project Planning

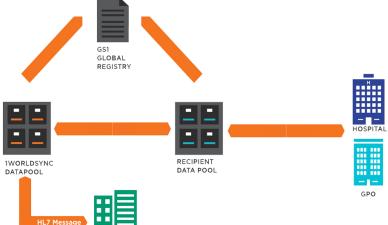


UDID population using **GDSN**

- Manufacturers can use the GDSN as a single point of for publishing an item's master data
 - Supply Chain and Market data to GPOs and Providers
 - UDID data to the FDA and other similar UDI databases globally
- Benefits to the approach
 - Single entry platform
 - Population of data one to many
 - GPOs and Providers receive UDID data elements
- GDSN has already made modifications for UDID
 - Additional attributes needed
 - Process flow for data pools to generate and

send SPL messages to the FDA







1WorldSync Solutions for Healthcare Manufacturers





Next Steps

- Contact GS1 US for company prefix assignment
 - **—** 937.435.3870
- Select a GDSN-certified Data Pool
 - Contact 1WorldSync at 1.866.280.4013 or 937.610.4223, or <u>businessdevelopment@1worldsync.com</u>
- Being loading your item information and synchronizing with your trading partners



Thanks for Attending!

Resources

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