



Lawson Healthcare Webinar World Series

October 27, 2009 – November 10, 2009

Healthcare Webinar World Series: www.lawson.com/hcwebinars

- ▶ **Tuesday, October 27**
The Basics of GS1 Data Standards in Healthcare – 11 am CST
- ▶ **Thursday, October 29**
Golden Opportunity: Lawson and GS1 Data Standards – 12 pm CST
- ▶ **Monday, November 2**
High Five for New Improved 9.0.1 Apps – 10 am CST
- ▶ **Tuesday, November 3**
On Point with a Smart Supply Solution – 10 am CST
Baylor Health Care System: Countdown to Mobile Supply Chain Success – 1 pm CST
- ▶ **Wednesday, November 4**
Inner Peace with Managed Services – 1 pm CST
- ▶ **Thursday, November 5**
Thomas Jefferson University Hospital: Feeling the Love with Lawson Workforce Management – 10 am CST
Penn State Hershey Medical Center: Streamlined and Stronger – 1 pm CST
- ▶ **Friday, November 6**
Accelerate the time to results with Lawson Learning Accelerator – 10 am CST
- ▶ **Tuesday, November 10**
Step Up to Lawson System Foundation 9.0.1 – 10 am CST
Optimize Your Workforce with Lawson Talent Management – 1 pm CST



Improving Patient Safety and Supply Chain Efficiency with Data Standards: The Basics of GS1 Standards in Healthcare

27 October 2009

Lawson's Involvement in Standards

- ▶ Since 2005, we've been involved in various standards initiatives and industry groups
 - Coalition for Healthcare eStandards
 - Healthcare Supply Chain Standards Coalition
 - Department of Defense GDSN Pilot

- ▶ Current involvement
 - GS1 Healthcare US
 - Strategic Marketplace Initiative

- ▶ Industry Education and Advocacy
 - Whitepaper published in January issue of Healthcare Purchasing News

- ▶ Working together with customers to include GS1 standards in our applications

Getting Started with Standards-Based Operating Procedures for Optimal Enterprise-Wide Supply Chain Management Performance

The goal of this white paper is to provide education on standards for location and product identification in the healthcare industry along with considerations for embarking on a standards integration project in your facility.

The U.S. healthcare industry now recognizes and acknowledges that the adoption of the product identification standards is one of the primary and most effective ways to solve many of the supply chain-wide challenges it experiences. Those challenges are caused by inaccurate data that directly contribute to higher costs and affect service level quality and efficiency, and can even compromise patient safety if critical resources are unavailable at the point of care, or if patient-specific identification errors occur.

Using data standards applied to patients, processes and products will enable healthcare facilities to accurately locate and identify what's needed as it is ordered, received, implemented and distributed within their facilities and throughout their organizations. The standards also enable the option to synchronize providers' item master databases with GS1, a worldwide organization that developed the global standards of unique product identification.

Data standards and synchronization processes have been successfully adopted and are in widespread use in many other industries worldwide. Proven benefits of supply chain standards include:

- Efficient traceability
- Improved order and invoice process
- Optimized receiving
- Accurate product identification and inventory levels
- Reduced data cleansing efforts
- Increased contract compliance with CPO distributors and the ability to monitor rebate levels
- Ability to better monitor product recalls and track expiration dates and product authentication
- Better data for customers throughout the facility to help with product selection decisions

According to a recent A.T. Kearney data synchronization paper, Procter and Gamble expects synchronization to save them a minimum of \$25 million a year by eliminating 50,000 to 50,000 hours per year in unnecessary transcription work, reducing stock-out incidence by 10%, and reducing the time required for new item introduction by 80% in the U.S. alone. An item synchronization pilot between Procter & Gamble and their customer H.E. Butt showed a 75% reduction in invoice deductions due to invoice pricing and product delivery discrepancies, 50% improvement in the number of accurate purchase orders received, 80% improvement in "speed to retail" for new items, price changes, and promotions, and 99.8% retail scanning accuracy achieved (versus 95% before the pilot).

Further driving standards adoption in the industry are changes to regulations. The FDA Amendments Act of 2007 that was signed into law on September 27, 2007, stipulates regulations establishing a unique device identification (UDI) system for medical devices requiring the label of devices to bear a specific identifier. This identifier should adequately identify the device through distribution and use, and may include information on the lot or serial number. The UDI would be applied at the "patient-use level" ("unit of use"); created and maintained by the manufacturer; constructed following GS1 or HIBC standards for device identification, and be human readable and encoded in a form of automatic identification technology. However the FDA did not mandate that a specific technology be identified.

Even so, the healthcare industry is embracing GS1 standards to be used for the unique identifier, with the official endorsement of GS1 standards by many leading healthcare associations, including the Association for Healthcare Resource & Materials Management (AHRMM) and the Coalition for Healthcare eStandards (CHES), which is now part of the Health Industry Group Purchasing Association (HIGPA), and a number of group purchasing organizations (GPOs). Consequently, it's a good time to evaluate your facilities' capabilities with your Materials Management Information System (MMIS) or Enterprise Resource Planning (ERP) system and the status of your current computing and software capabilities that will allow you to move forward in the adoption and ongoing implementation of these standards.

While the GS1 standard system is not new to most industries throughout the world, it is new to healthcare in the U.S. The FDA has not stipulated a firm timetable for healthcare facilities to be able to track these codes – but it will be in the next few years, according to a FDA spokesman.

The terms you need to know!
 The GS1 organization (formerly the Uniform Code Council or UCC) is the leading global standards organization in the healthcare industry, supporting the healthcare community through its GS1 Healthcare global initiative.

GS1 Healthcare is a voluntary, global user community that brings together all healthcare stakeholders, including: pharmaceutical and medical device manufacturers, wholesalers and distributors, group purchasing organizations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies, and associations.

GS1 has defined the key terms in its standardization pathway as:

- GLN (Global Location Number) – the globally unique GS1 Identification Number for locations and supply chain partners. The 13-digit GLN can be used to identify a functional entity (like a hospital, pharmacy or accounting department), a physical entity (like a warehouse or hospital wing or even a nursing station), or a legal entity (like a health system corporation). The attributes defined for each GLN (e.g., name, address, class of trade, etc.) help users to ensure that each GLN is specific to one, very precise location within the world.
- GTIN – (Global Trade Item Number) – the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be sold, delivered or invoiced at any point in the supply chain). The 14-digit GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The attributes defined for each GTIN (e.g., size, weight, package, etc.) help users to ensure that each GTIN is specific to one, very precise trading unit configuration (e.g., a blister of two aspirin tablets; a bottle of 100 aspirin tablets; etc.).
- GDSN – (Global Data Synchronization Network) – The GDSN is a network of interoperable data pools connected by the GS1 Global Registry. The GDSN uses the GS1 identification and data standards as the common language for supply chain information. Specifically, the GDSN uses the GLN for information about supply chain partners and/or locations, and the GTIN for information about products.
- UNSPSC – (United Nations Standard Products and Services Code) – A hierarchical set of product categories used by supply chain partners worldwide to classify their products and services. Use of the UNSPSC enhances company-wide visibility of spending analysis and promotes cost effective procurement.

Ultimately, implementation of GS1 standards promises to eliminate custom account



Jean Sargent, CMRP, FAHRMM
Director Supply Chain, USC Health Sciences
AHRMM President 2007
GS1 Healthcare US Leadership Team

**Please note: This session is being recorded. Due to limited Q&A time we may be unable to address all questions. If you have a question that has not been answered, please forward via email for response:
*GS1HealthcareUS@gs1us.org***

Introduction to GS1 Healthcare US



Who is GS1[®]?



Who is GS1 US[™]?



GS1 Healthcare – Global Standards



**GS1 Healthcare US[™] – Standards
Implementation**



Who is GS1?

▶ **GS1** is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **108** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world



Who is GS1 US ?

- ▶ **Formerly Known as the UCC**
 - Established **1973** (*think U.P.C.*)
- ▶ **Implements the GS1 System in the U.S.**
 - **23** industries, **200,000** members in U.S.
 - **1 million** global members, **150** Countries
 - **16,000** identified healthcare members in U.S.
 - Uniquely identify products, assets, and locations
 - Bar codes, EPC, e-Commerce, UNSPSC®
- ▶ **Voluntary, Not-for-Profit, Neutral, Member Driven**

GS1 Standards in Healthcare

Five Patient Rights
Right Patient
Right Drug/Device
Right Time
Right Dose
Right Route

- ▶ **Enable traceability and authentication systems**
 - Fight counterfeiting
 - Effective & efficient product recalls
 - Improve supply chain efficiency
- ▶ **Enable AIDC systems all the way to the point-of-care or point-of-sale**
 - Ensure the 5 patient rights
 - Reduce medication errors
 - Improve supply chain efficiency
- ▶ **Enable regulatory compliance**
 - Pedigree legislation in California, etc.

GS1 Healthcare

GS1 Healthcare is a **voluntary**, global user community bringing together all healthcare stakeholders.

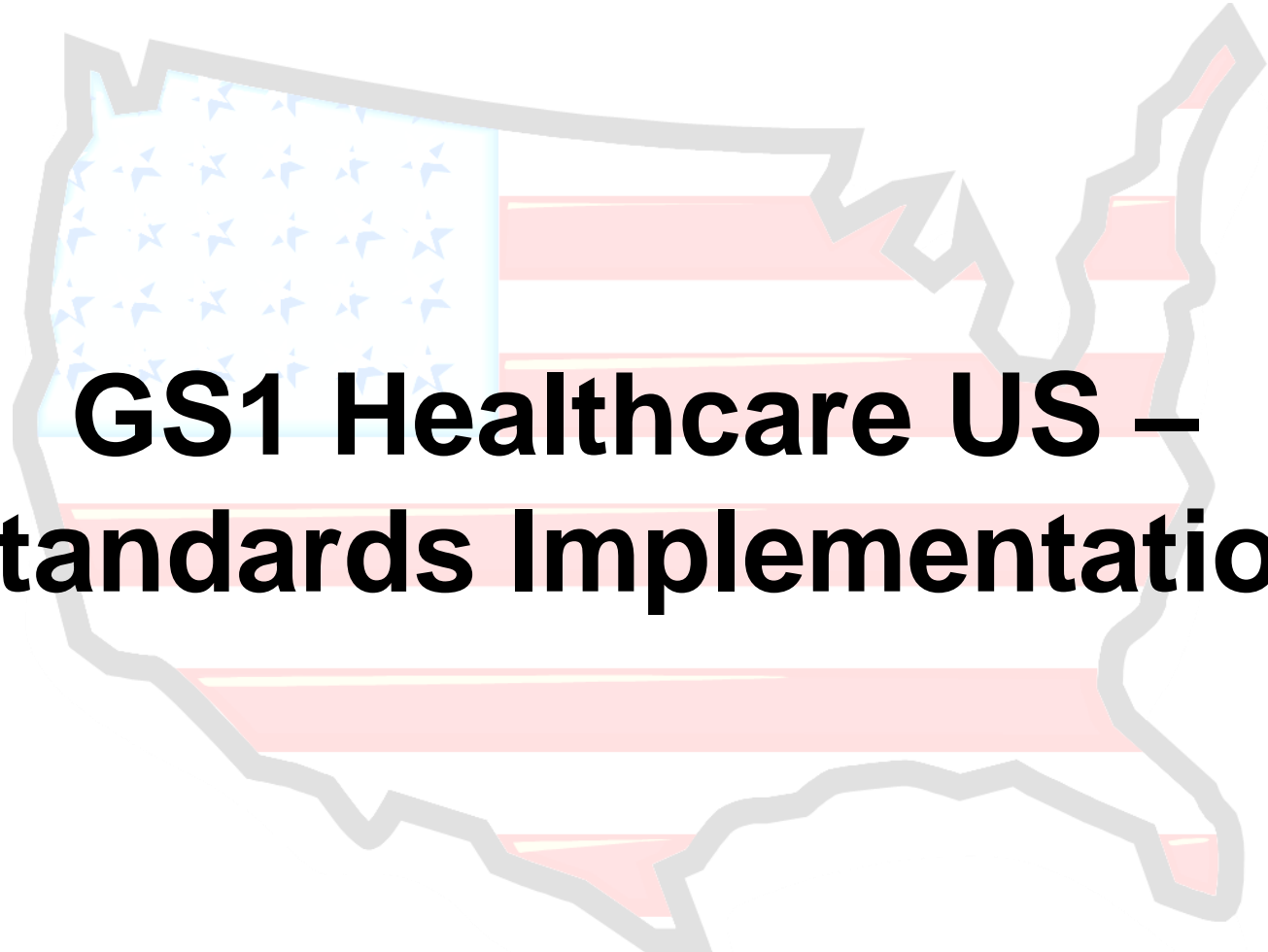
Manufacturers ♦ Wholesalers ♦ Distributors Hospitals ♦ Pharmacies ♦ Regulatory Bodies ♦ Trade Associations ♦ GS1 Member Organisations

2009 Leadership Team

 Abbott <small>A Promise for Life</small> Mike Wallace	 Alcon Grant Hodgkins	 B. BRAUN <small>SHARING EXPERTISE</small> Volker Zeinar	 Genzyme <small>Genzyme</small> Frédérique Fremont	 COVIDIEN Co-Chair: Mark Hoyle		
 CVS CAREMARK Ramesh Murthy	 gsk <small>GlaxoSmithKline</small> James Hickland	 Johnson & Johnson Tom Werthwine	 MCKESSON <small>Empowering Healthcare</small> Ron Bone	 Medtronic <small>Alleviating Pain • Restoring Health • Extending Life</small> Jackie Elkin		
 NOVARTIS Scott Cameron	 Pfizer Co-Chair: Tim Marsh	 PREMIER Joe Pleasant	 smiths medical <small>bringing technology to life</small> Jim Willmott	 GS1 <small>in Europe</small>	 GS1 <small>US</small>	 GS1 <small>Japan</small>

Local Healthcare User Groups Driving Adoption





GS1 Healthcare US – Standards Implementation

108 Member Companies

Industry Associations (17)

- AAP - American Academy of Pediatrics
- AHA - American Hospital Association
- AHRMM - Association for Healthcare Resource and Materials Management
- ASHP - American Society of Health-System Pharmacists
- CHPSO - California Hospital Patient Safety Organization
- CHSCR - Center for Healthcare Supply Chain Research
- Dental Trade Alliance
- GHVRHIO - Greater Hudson Valley Regional Health Information Organization
- GPhA - Generic Pharmaceutical Association
- HDMA - Healthcare Distribution Management Association
- HIDA - Health Industry Distributors Association
- Medical Device Supply Chain Council
- MITA - Medical Imaging & Technology Alliance
- NACDS - National Association of Chain Drug Stores
- NCPD - National Coalition of Pharmaceutical Distributors
- NCPDP - National Council for Prescription Drug Programs
- SMI - Strategic Marketplace Initiative

Manufacturers (20)

- Abbott Laboratories, Inc.
- Baxter International, Inc.
- Becton Dickinson
- Boehringer Ingelheim USA
- Bristol-Myers Squibb Company
- Covidien
- C.R. Bard
- GE Healthcare
- Genzyme Corporation
- GlaxoSmithKline
- Johnson & Johnson
- Kimberly-Clark Corporation
- Medical Action Industries
- Medline
- Medtronic, Inc.
- Merck & Company, Inc.
- Novartis Pharmaceuticals Corporation
- Pfizer, Inc.
- Sage Products, Inc.
- Talecris Biotherapeutics, Inc.

108 Member Companies

Solution Providers (25)

- Accenture
- Acsis, Inc.
- AXWAY
- BravoSolutions
- Clarkston Consulting
- Craneware, Inc.
- D2 Pharma Consulting LLC
- DataPros for Healthcare
- Deloitte Consulting
- ECRI Institute
- GHX
- Lansa, Inc.
- Lawson Software
- Loftware, Inc.
- MediClick, Inc.
- Noblis
- PharmTech, Inc.
- Product Identification & Processing Systems, Inc.
- rfXcel Corporation
- SAP AG
- Supplyscape Corporation
- Systech International
- Tecsys, Inc.
- Vendormate, Inc.

Retailers (1)

- CVS Pharmacy

Distributors (4)

- AmerisourceBergen Drug Corporation
- Cardinal Health
- McKesson
- Owens & Minor

Academic Institutions (2)

- CIHL - Center for Innovation on Healthcare Logistics
- Wright State Research Institute

Government Agencies (4)

- DMSB - Defense Medical Standardization Board
- DoD/DMLSS - Defense Medical Logistics Standard Support
- Dept. of Veteran Affairs
- FDA - US Food and Drug Administration

Group Purchasing Organizations (7)

- Amerinet
- Consorta
- GNYHA Services
- HealthTrust Purchasing Group
- MedAssets
- Novation LLC
- Premier, Inc.

Hospitals/IDNs (29)

- Ascension Health
- Atlantic Health
- BJC Healthcare
- Carolinas Healthcare System
- Catholic Health Initiatives
- Geisinger Health System
- Intermountain Healthcare
- Johns Hopkins Health Systems
- Kettering Health Network
- Louisiana State University Health Sciences Center
- Mayo Clinic
- Ministry Health Care Inc.
- Munroe Regional Medical Center
- New York Presbyterian Hospital
- OSF Healthcare System
- PeaceHealth
- Premier Health Partners
- Ridgeview Medical Center
- Sentara Healthcare
- Sisters of Mercy ROI
- SSM Healthcare
- Surgical Care Affiliates
- The Ohio State University Medical Center
- UK Healthcare
- University of Mississippi Medical Center
- University of Virginia Medical Center
- University of Wisconsin Medical Foundation
- University Southern California Health Sciences
- Wellspan Health

GS1 Healthcare US Leadership Team

Healthcare Category*	Term ends 12/31/09	Term ends 12/31/10
Acute Care Provider	Joe Dudas Mayo Clinic	Jean Sargent USC Health Sciences
Alternate Site Provider	Vacant	Mary Ann Michalski Surgical Care Affiliates
Distributor	Ron Bone McKesson	Bill Zimmerman Cardinal Health
GPO	Mary Beth Lang Amerinet	Dennis Byer Novation
Healthcare Assns, Education, Government, Solution Providers**	Debbie Sprindzunas AHRMM	Dennis Orthman SMI
Medical Device Manufacturer	Dennis Black Becton Dickinson	Roy Ludvigsen Kimberly-Clark Corp
Pharmaceutical Manufacturer	Mike Rose Johnson & Johnson	Peggy Staver Pfizer, Inc
Retail Pharmacy	Vacant	Ramesh Murthy CVS Pharmacy
Ex-Officio Guests (non-voting)***	Steve Perlowski NACDS	Perry Fri HDMA

**Two representatives allowed for each category: (1) one-year term & (1) two-year term*

***Non voting members*

****Through December 31, 2009*

Same Product – Different Numbers*

Industry Distributor Numbers for 3M Product # 8630:

- ▶ Allegiance - M8630
- ▶ Owens & Minor- 4509008630
- ▶ BBMC-Colonial- 045098630
- ▶ BBMC-Durr - 081048
- ▶ Kreisers - MINN8630
- ▶ Midwest - TM-8630
- ▶ Pacific - 3/M8630
- ▶ UnitedUMS - 001880

Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.



* Source: Department of Defense Data Synchronization Study

Same Number Different Products*

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

■ Part Number: 10313
refers to:

Medtronic's - "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"

Hantover's - "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"

Chattanooga Group's - "ACCESSORY TRACTION REPLACEMENT STRAP XL FOR HALTER THORACIC RESTRAINT"

HF Scientific's - "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

■ Part Number: 1050 refers to:

3M Company's - "DRAPE INCISE 35 3/8X 17 5/8IN"

Tyco's - "PAD TELFA 3 X 4IN STER"

* Source: Premier Inc. Product Item Master

What is the pain?

Too many identifiers for the same healthcare location
= **Confusion, finger pointing, & inefficiency**

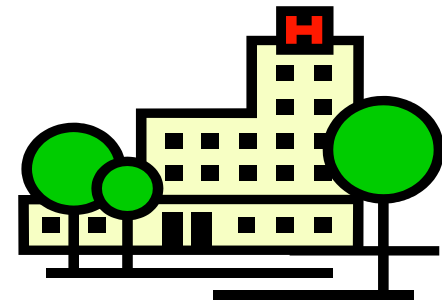
▶ **ST** JOHN'S QUEENS HOSPITAL
100084547

▶ SAINT **JOHNS** QUEENS HOSPITAL
JAOE

▶ SAINT JOHN'S **QUEEN** HOSPITAL
50003000431

▶ SAINT JOHN'S **QUEEN'S** HOSPITAL
CA2053

▶ **ST.** JOHN'S QUEENS HOSPITAL
OM 12345

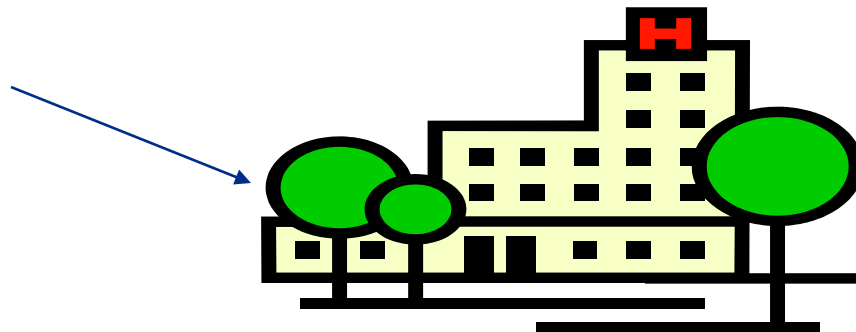


**Many different names
and location numbers
for 1 hospital**

GLN Registry for Healthcare[®]

▶ SAINT JOHN'S QUEENS
HOSPITAL

▶ 1100004570208



**One standard locator GLN with
address rationalized through
US Postal Service**

The GS1 System

3G's and U

- ▶ GTIN Product Identification
- ▶ GLN Location Identification
- ▶ GDSN Data Attribute Accuracy

and

- ▶ “UNSPSC®” Product Classification

Provider Tool Kits: GTIN, GLN, GDSN, UNSPSC

- ▶ Introduction to the Standards
- ▶ Implementation Steps
- ▶ Lessons Learned
- ▶ Benefits to Healthcare Providers
- ▶ ROI Hot Spots
- ▶ FAQs
- ▶ www.gs1us.org/hcptoolkit



New! Supplier Tool Kits: GTIN, GLN, GDSN

- ▶ Introduction to the Standards
- ▶ Implementation Steps
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- ▶ ROI Hot Spots
- ▶ FAQs
- ▶ www.gs1us.org/hcsuptoolkit

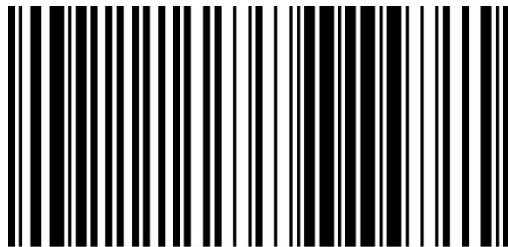


What is a GTIN®?

- ▶ GTIN is Global Trade Item Number
- ▶ A globally unique 8, 12, 13, or 14-digit number that uniquely identifies products and services
- ▶ An identification number of the GS1 System, therefore unique and unambiguous
- ▶ A global standard for collaborative commerce
- ▶ A 14-digit GTIN is encoded in a GS1-128/DataMatrix /Databar

/Databar

GS1 -128 (14-digit GTIN)



(01) 0031414199995

DataMatrix (14-digit GTIN)



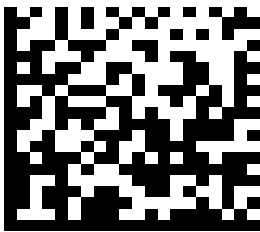
(01) 0031414199995

Databar (14-digit GTIN)



(01) 0031414199995

GTIN: Healthcare Example



(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

GTIN (Global Trade Item Number)

Expiry Date

Lot Number

Serial Number



2012 GTIN Sunrise

“Adoption of GTIN in Healthcare by 2012*”

Global Trade Item Numbers (GTINs)**

- GTINs are assigned to healthcare products
- GTINs are used in business transactions
- GTINs are marked on appropriate packaging levels
- GTINs are scanned at points-of-delivery to enhance clinical process
- GTINs are used in product returns and recalls
- GTINs are registered in a GS1 GDSN-certified Data Pool

**December 2012*

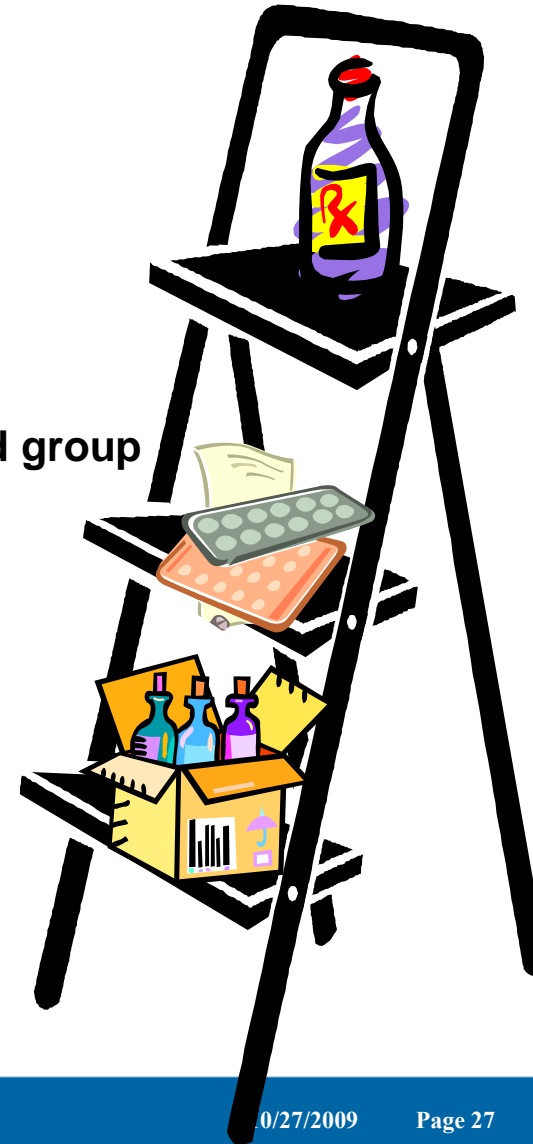
***Unique Product Identifiers*

Traceability Ladder of Precision

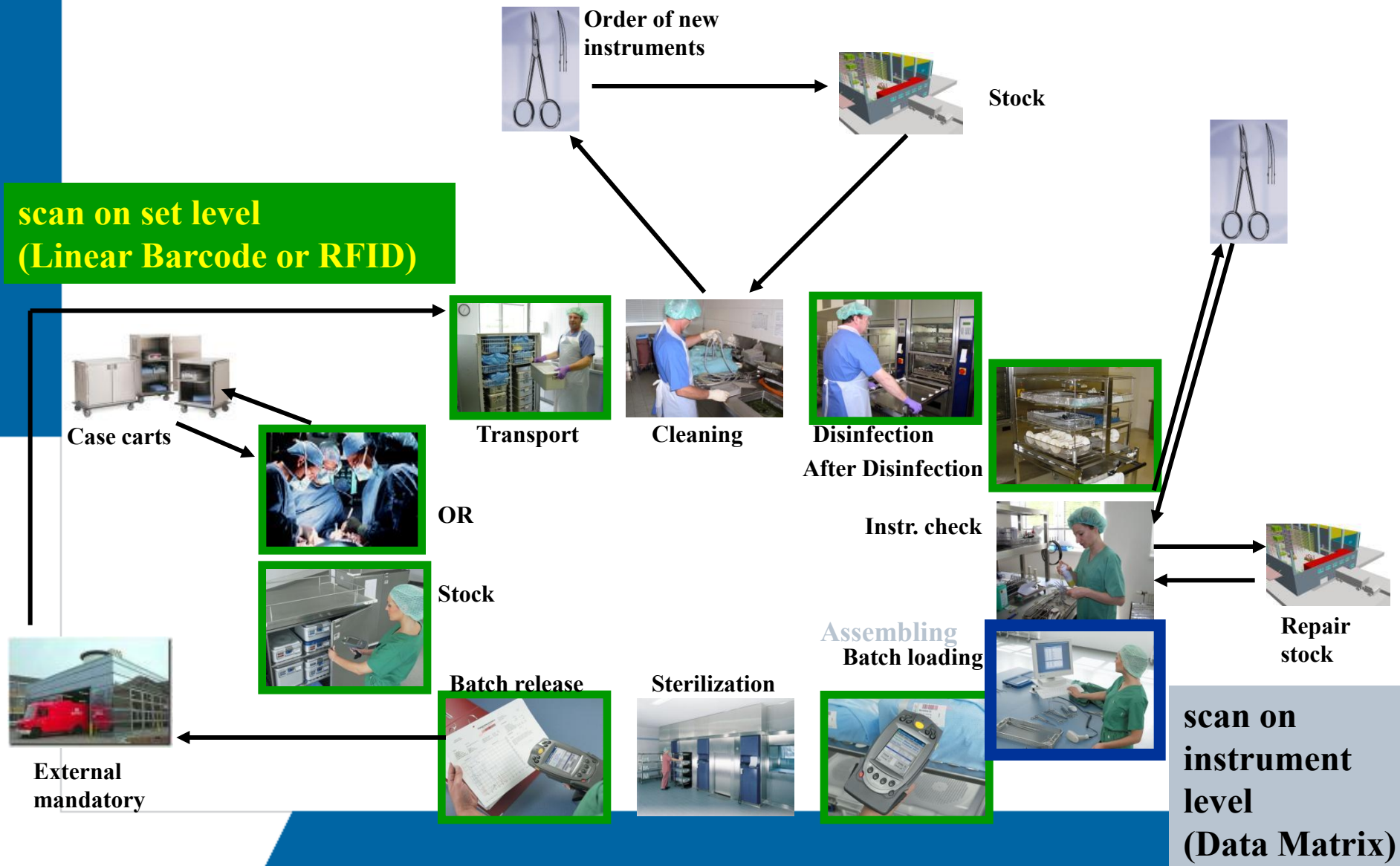
- ▶ **GTIN and Serial Number identifies a precise product and packaging size**
 - 1 0300710362403 (21) 123456asd
 - Dilantin Blister
 - Serial Number 123456asd

- ▶ **GTIN and Lot Number identifies Products within a defined group**
 - 1 0300710362403 (10) 05724f
 - Dilantin Blister
 - Lot number 05724F

- ▶ **GTIN identifies product and package**
 - 1 0300710362403
 - Dilantin Blister



Micro Logistic means: Instrument Reprocessing Cycle



2012 GTIN Sunrise

“Adoption of GTIN in healthcare by 2012”

	Phase One Awareness	Phase Two Notify Trading Partners	Phase Three Contract & Systems	Phase Four Transaction	Phase Five 2012 Implementation
Provider & GPO	Know GS1 System Standards. Review internally what must be changed to accept.	Notify trading partners of need for GTIN, and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number) and ask their ability to meet it.	Terms and condition of contracts specify applicable GS1 Standards, specifically GTINs. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards.
Distributor	Know GS1 System Standards. Review incoming material and the ability of internal systems to accept.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	Terms and conditions of contracts specify applicable GS1 Standards on products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered, received and shipped are marked in accordance with GS1 Standards.
Suppliers	Know of impending requirement, access ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	Terms and conditions of contracts call for GS1 Standards on all products: GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards and have the minimum number of data attributes loaded into a shared data catalog (e.g. GDSN).
Software Providers	Know of impending requirement, access ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from suppliers.	GS1 Standards are imbedded in all products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority if not all transactions and software has been developed to support.	All products have specific segments identified for GS1 Standards, following allocation rules in the specifications.

FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

- The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

Medical Device Adverse Events

For 2007, we received ~ +100k reports

- ▶ ~ 15% lacked model or catalogue number
- ▶ ~ 50% lacked lot or other identifier
- ▶ ~ 10% lacked both

The face of things to come...

(01)00802526255410(17)080531(10)6062151

Medical Device Recalls (2007)

41 Class I recalls

931 Class II recalls

78 Class III recalls

Class I – 28M units (devices by lots, kits, etc)

Range 4-27M (Moistureplus Solution)

For March 2007 – 142 Class II recalls

35M individual units (just one month)

Range 1-33M (Lifescan one touch test strips)

FDA - Medical Device Identification

Develop a system to identify medical devices which is:

- ▶ Consistent
- ▶ Unambiguous
- ▶ Standardized
- ▶ Differentiates along all identification dimensions
- ▶ Unique at all levels of packaging
- ▶ Harmonized internationally

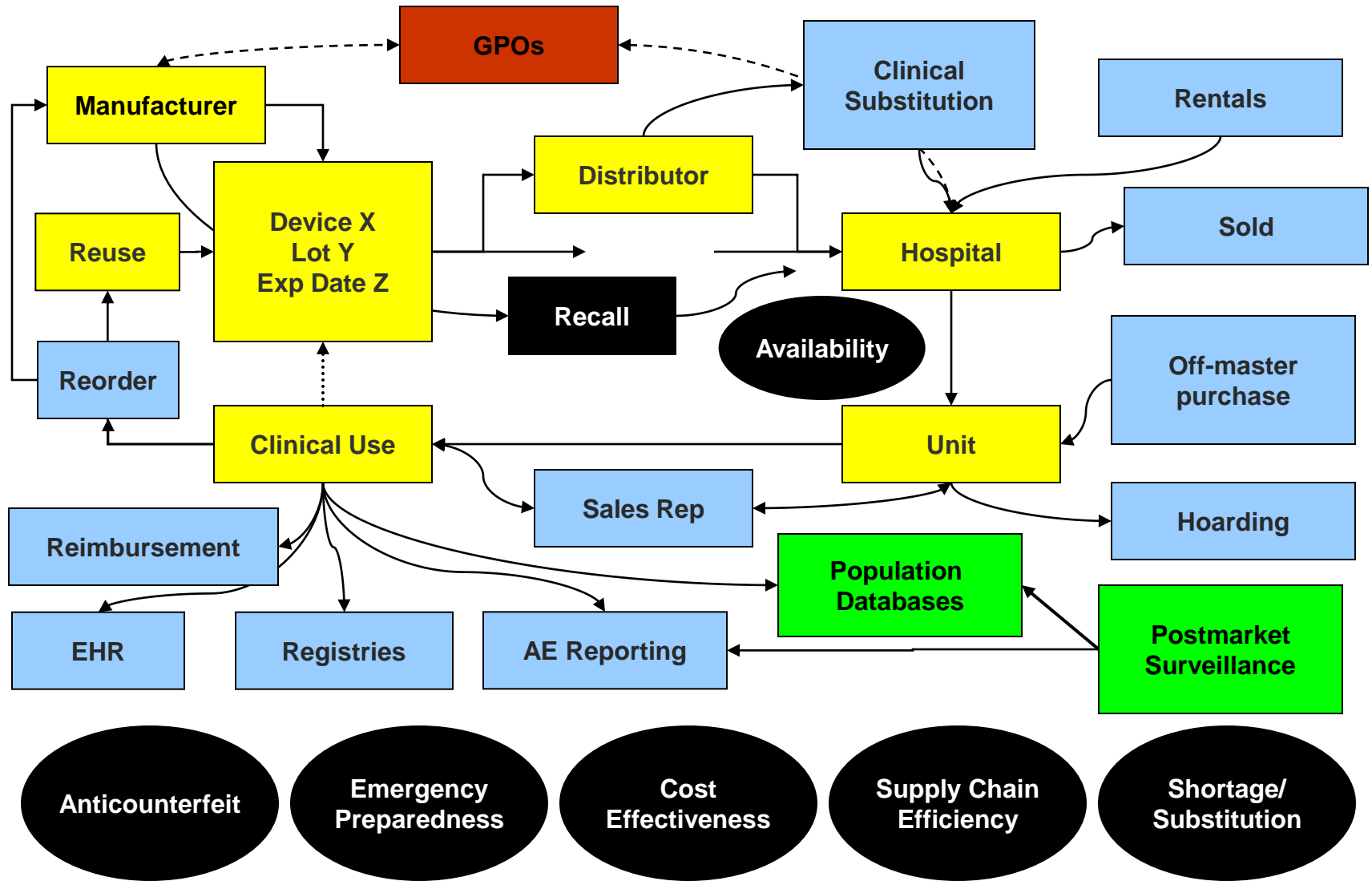
FDA - UDI Can Improve...

- ▶ Medical device recalls
- ▶ Adverse event reporting and postmarket surveillance
- ▶ Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- ▶ Disaster/terror preparation and shortages/substitutions
- ▶ Systems to reduce medical errors
- ▶ Assisting clinicians in identifying appropriate device
- ▶ Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- ▶ Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

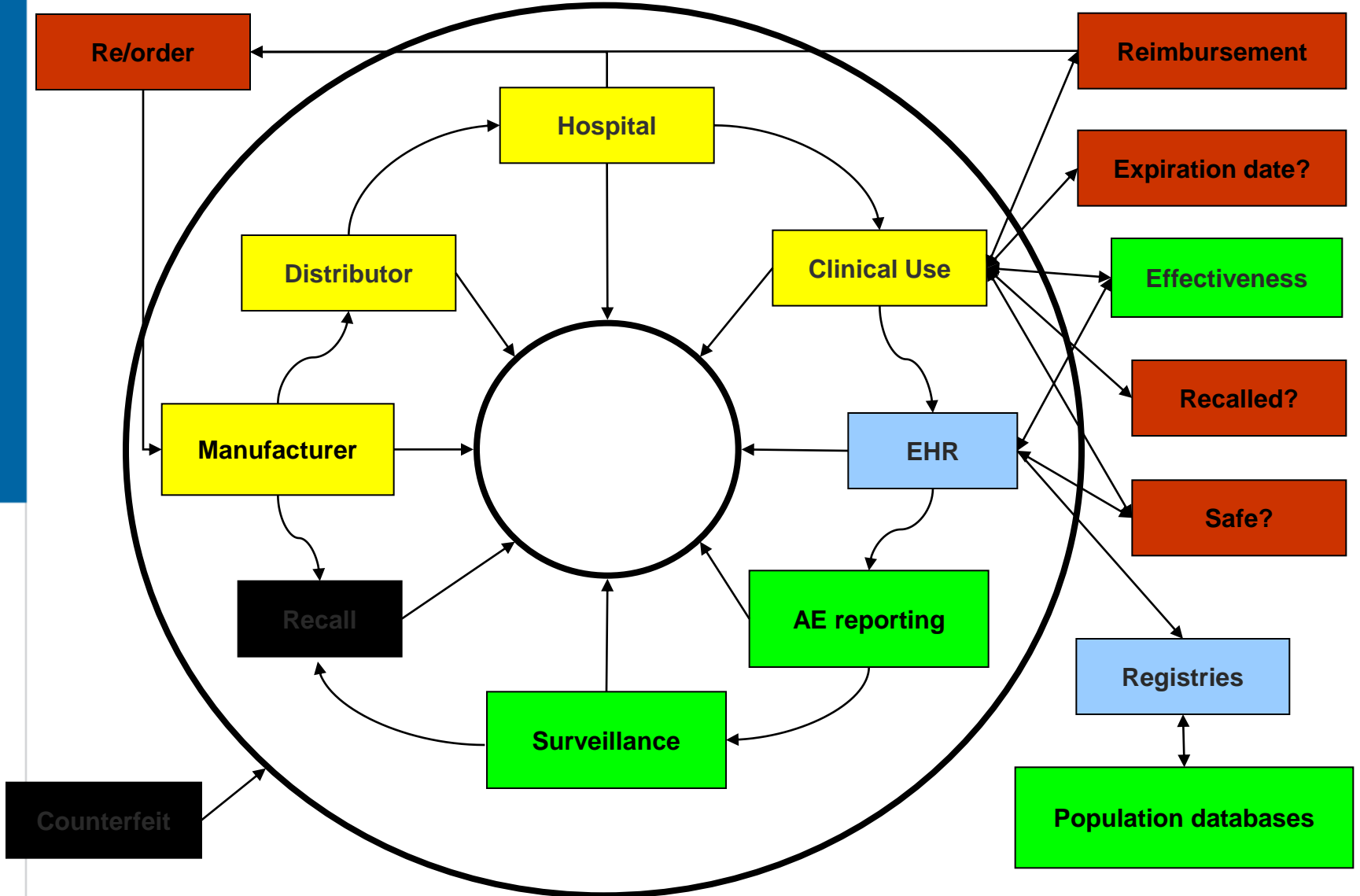
FDA - Other UDI Issues

- AutotID technology issues
- Kits; combination products; legacy devices
- Re/marking (legally) reprocessed SUDs
- Hospital and other healthcare facility uptake
- Remanufactured and refurbished devices
- Triggers requiring a new UDI
- Complex, multi-system (“capital”) devices
- Harmonized/international database

FDA - Device Information Lifecycle



FDA - Future Information Lifecycle



Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

Email: cdrhudi@fda.hhs.gov

What is GLN? Global Location Number

- ▶ A globally unique 13-digit number that identifies:
 - ▶ Legal entities
 - Whole companies, health systems, divisions
 - ▶ Functional entities
 - Specific department within a legal entity, (e.g., pharmacy, receiving department, etc.)
 - ▶ Physical locations
 - Clinics, units, warehouses, loading docks, etc.
- ▶ Used instead of phone numbers, store numbers, DUNS+4, etc.
- ▶ A global standard of the GS1 System for collaborative commerce

GS1 Member GLN

- ▶ 13-digit number

- ▶ Components:

1. GS1 Company Prefix - Varies in length

2. Location Reference number

Assigned by the company


3. Check Digit

- *Can also be assigned randomly by GS1 US*

- *No intelligence*

- *Maintenance*

Combined
length is
always 12
digits



GLN Registry for Healthcare® Health System Example

The screenshot displays the 'GLN Registry for Healthcare' web application interface. The browser title bar shows 'GLN Registry for Healthcare'. The main content area is titled 'Location Maintenance' and features four tabs: 'Search', 'Edit', 'New', and 'Audit'. Below these tabs is a hierarchical tree structure of healthcare locations, each with a small icon and a unique identifier in parentheses. The tree starts with 'GEISINGER HEALTH SYSTEM FOUNDATION (1100002569136)' at the top, which branches into several sub-locations including 'GEISINGER CLINIC (1100002376260)', 'GEISINGER COMMUNITY HEALTH SERVICES (1100005054301)', and 'GEISINGER HEALTH PLAN (1100003274978)'. The 'GEISINGER HEALTH PLAN' further branches into 'GEISINGER HEALTH PLAN MARKETING (1100003889097)', 'GEISINGER HEALTH PLAN MOOSIC (1100002656515)', 'GEISINGER HEALTH PLAN STATE COLLEGE (1100002345242)', and 'GHP MARKETING AND SALES (1100005018693)'. Other locations listed include 'GEISINGER HEALTH SYSTEM ACCOUNTS PAYABLE (1100003779374)', 'GEISINGER MEDICAL CENTER (1100004348319)', 'GEISINGER MEDICAL MANAGEMENT CORPORATION (1100002504182)', 'GEISINGER SOUTH WILKES BARRE (1100004854773)', 'GEISINGER SYSTEM SERVICES (1100004963093)', 'GEISINGER WYOMING VALLEY MEDICAL CENTER (1100005700116)', 'Geisinger Health System Foundation Affiliates (1100005947894)', and 'MARWORTH (1100004689528)', which includes 'MARWORTH TREATMENT CENTER (1100004738646)'. At the bottom of the main area are two tabs: 'Info' and 'Hierarchy'. On the left side, there is a vertical navigation menu with buttons for 'Locations', 'Users', 'Subscriptions', 'Notifications', 'Reports', 'Exports', 'Import', 'Location Settings', 'Add New GPO', 'Help', and 'Print Screen ->'. Below the menu, it shows 'Logged In As: UCC Super User At: 5/14/2009:14:39:51' and a 'Logout' button.



2010 GLN Sunrise

“Adoption of GLN in Healthcare by 2010*”

Global Location Numbers (GLNs)**

- GLNs are assigned by location owners
- GLNs are used in appropriate business transactions and processes between trading partners
- GLN hierarchy is defined and maintained by location owners
- GLN Registry for Healthcare® is used to facilitate correct location identification

**December 2010*

***Unique Location Identifiers*

2010 GLN Sunrise

“Adoption of GLN in Healthcare by 2010”



	Provider	Supplier	GPO
	<ul style="list-style-type: none"> * Certifies accuracy of data and maintains in real time as business partners rely exclusively on the accuracy of this data. * Assumes responsibility for enumeration of locations to ship-to, bill to, and pay from level with GLNs. 	<ul style="list-style-type: none"> * Provider maintains data in registry “real” time. * Begin to utilize GLN to identify business partners in internal systems. * Work with business partners to align existing account numbers to GLN. 	<ol style="list-style-type: none"> 1. Agreements between the manufacturer/distributor and GPO should have membership rosters submitted with the GLN as the identifier and the applicable demographics for their membership and that payments back to the GPO include the GLN and demographics. 2. Agreements between the manufacturer and IDN/Single Facility should reference the customers covered using their GLN and demographics. 3. Agreements between the manufacturer and distributor/wholesaler should detail electronic transactions. The use of 832 (Price Sales Catalog) & 845 (Price Authorization) should reference GLNs. 4. Agreements between the distributor/wholesaler and IDN/Single Facility should use GLNs. Provider agreements with their trading partners should include locations (address) listing as appropriate. 5. Recommend GLNs replace custom identifiers with GLNs in these processes for both electronic and EDI transactions (purchase orders, Advance Ship Notice, etc.): <ul style="list-style-type: none"> -850 (Purchase Order[PO])/855 (Reply to PO)/860 (PO Change Request)/856 (Advanced Ship Notice) first priority, scalable and repeatable -810 (Invoice) later in process. 6. Replacement of GLNs in paper transactions should follow as business partners are technically capable.
	<ul style="list-style-type: none"> * Certifies accuracy of data and maintains real time. * Enumerates the order from and pay to locations with GLNs. 	<ul style="list-style-type: none"> * Begin to utilize GLN to identify business partners in internal systems. * Work with business partners to align existing account numbers to GLN. * Align existing account numbers and GPO proprietary ID to GLNs, where applicable. 	<ol style="list-style-type: none"> * Maintain GLN hierarchy in registry “real” time, resulting in database or record for business partners’ communication. * Becomes final arbiter of GLN and all disputes are adjudicated via provider.
	<ul style="list-style-type: none"> * Initially enumerates locations at ship-to level until the provider assumes responsibility. * Assists provider members with education, hierarchy design and general enumeration strategy. * Display ship-to locations with GLNs within their roster. * Adjudication assistance to members, but final decision is made by provider. 	<ul style="list-style-type: none"> * Work with business partners to align existing internal account numbers to the GLN number. 	<ol style="list-style-type: none"> * Maintain info in systems utilizing GLN, ship/order/sales tracing/contracts. * Access registry to maintain location information and accept final judgment of provider on accuracy of GLN.
			<ul style="list-style-type: none"> * Maintain roster membership lists using only GLN, reporting/fees done by GLN. * Adjudication assistance to members, but final decision is made by provider.

What is GDSN?

Global Data Synchronization Network

GS1 Global Registry®

The GDSN acts as a "yellow pages directory" that:

- Provides information for subscription sharing
- Enables Data Pool interoperability

Guarantees uniqueness of the registered items and parties

Ensures that all Data Pools in the network comply with a common basic set of validation rules that support data integrity in the system

Holds the information about who has subscribed to trade item or party data

Seamless integration from manufacturer to distributor to provider

Key Elements of the GDSN

GDSN-certified Data Pools

Electronic catalogues of standardized item data, serving both as a source and/or recipient of master data.

Can be run by a GS1 Member Organization, supplier, customer, exchange or service provider.

GTINs within GDSN

To begin the data synchronization process, GTINs are provided to a GDSN-certified Data Pool.

GTINs: Used to uniquely identify products

- ▶ GDSN prevents duplicates

GTIN: “Key” in the Data Pool

- ▶ Product data attributes are linked to the GTIN

GTINs: Synchronized

- ▶ Defined once and used until changed or deleted

Required GDSN Attributes

GTIN	Consumer Unit
Pack Level	Orderable Unit
Manufacturer Part Number	Invoice Unit
Parent GTIN	Shipping Unit
Child GTIN	Base Unit
Quantity of Children	Variable Unit
Publisher GLN	Returnable Package
Target Market	Marked with Lot Number
Brand Owner & GLN	Bar Code Type
Manufacturer Name & GLN	GPC Code
Functional Name	Optional Classification Agency & Value
Brand Name	Start Date
Description	Effective Date
Height	Shelf Life from Production
Width	Shelf Life from Delivery
Depth	
Gross Weight	
Net Content	

GLNs within GDSN

The first step in utilizing a Global Data Synchronization Network (GDSN) Data Pool is registering your organization's GLNs

The GLN is required to uniquely identify your organization

Depending on your business structure, you may have one or more GLNs registered

The GLN identifies where information is being sent (e.g., a hospital) and who owns the information (e.g., a supplier)

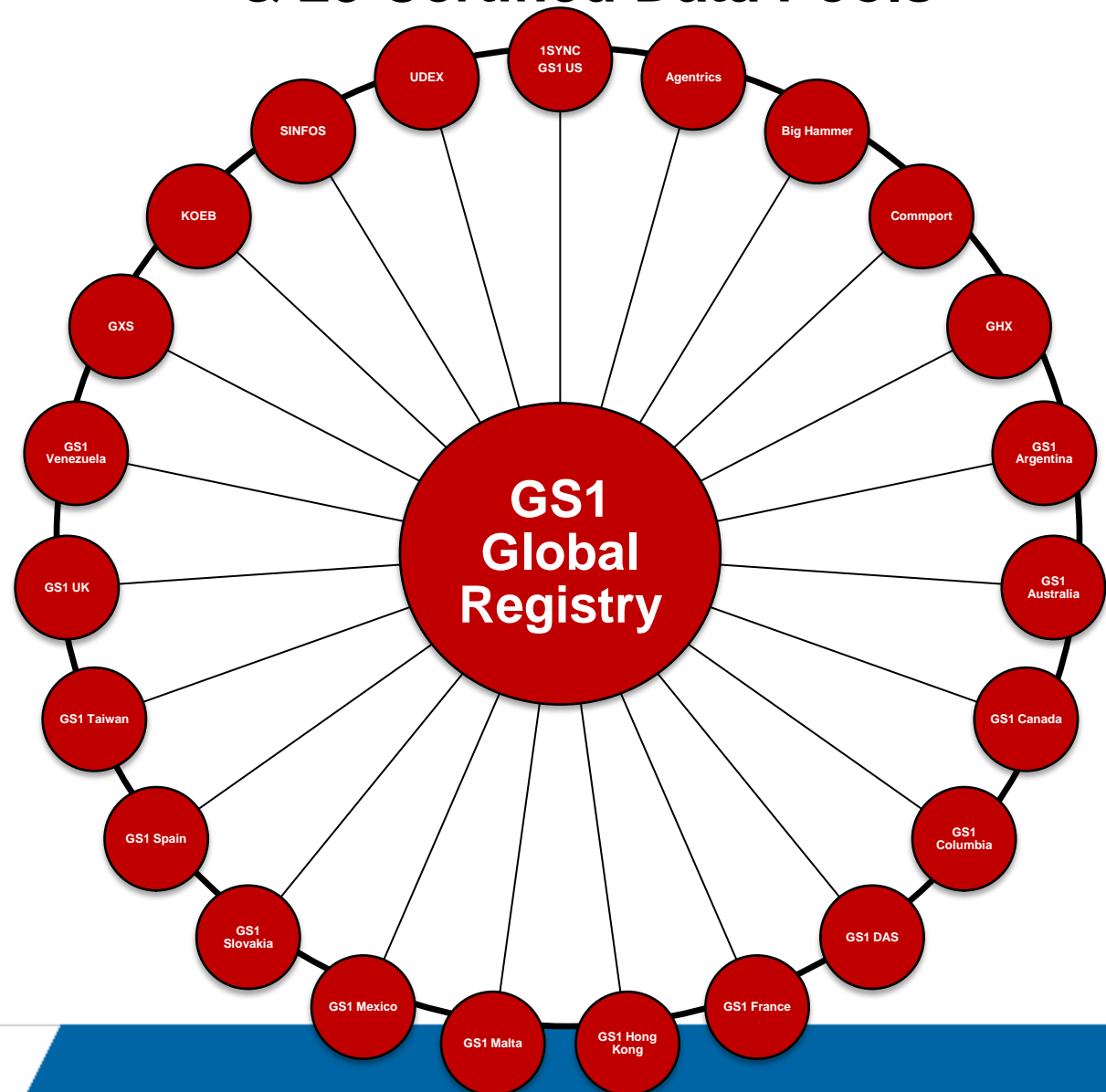
Why Are These Standards Important?

A few examples ...

- ▶ Electronic commerce, such as EDI – ensures accurate product data to be used for more types of business transactions and interoperability
- ▶ Data Synchronization – healthcare needs to be able to synchronize product data – globally
- ▶ Serialization – ability to know *where and when* a trade item is, based again, on a global standard
- ▶ Decreasing counterfeiting of grey and black market sales – therefore improving patient safety
- ▶ Contracting and compliance – sourcing product data with improved accuracy
- ▶ Enables regulatory compliance with less costs and more efficiencies:
 - Medical device recalls, adverse reporting, track and trace, disaster/terror preparation and device shortages, reduce medical errors, and document medical device use in EHR/PHR

And much more ...*but trading partners must facilitate this data!*

The GS1 Global Registry & 23 Certified Data Pools



GDSN US Data Pools for Healthcare



1 SYNC

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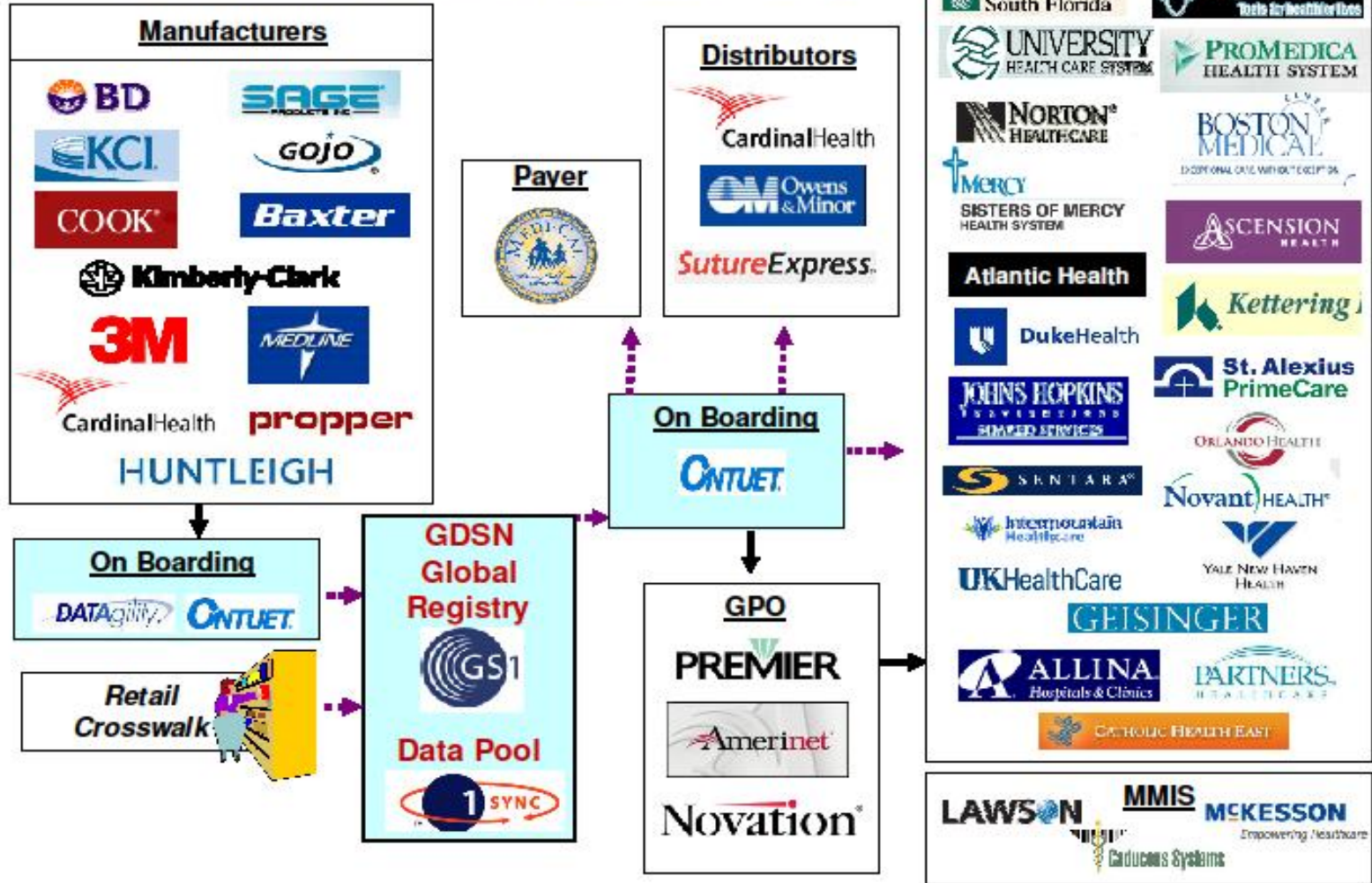
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DoD Healthcare GDSN Pilot



United Nations Standard Products & Services Code[®] (UNSPSC)

An open, global, multi-industry standard

Used to classify products and services

Provides a structure or framework for product classification

Provides a way to categorize products and services to help users organize products for catalogs, databases and listings

Owned by: United Nations Development Programme (UNDP)

Managed by: GS1 US (6 years)

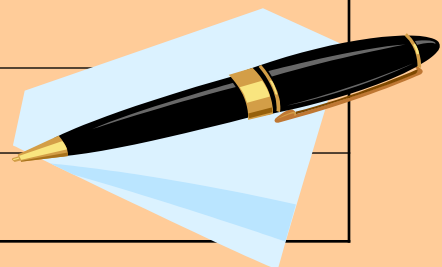
Designed to facilitate electronic commerce

- ▶ Help streamline the procurement process
- ▶ Help analyze spending
- ▶ Help customers find products

United Nations Standard Products and Services Code (UNSPSC) (Overview & Example)

Using the Codeset

<i>Hierarchy</i>	<i>Category Number and Name</i>
Segment	44 - Office Equipment and Accessories and Supplies
Family	10 - Office machines and their supplies and accessories
Class	11 - Office and desk accessories
	15 - Mailing supplies
	16 - Desk supplies
	17 - Writing instruments
Commodity	04 - Ball Point Pens



44101704 : Ball Point Pens

GS1 Healthcare US™ - Workgroups

Workgroup		Workgroup Participants
1.	Product Identification (GTIN)®	81
2.	Location Identification (GLN)	119
3.	GDSN® Implementation	95
4.	Traceability Adoption	115
5.	Application & Implementation	34

Current Workgroup Initiatives

Supplier Tool Kits (GTIN, GLN, GDSN)

Product Identification (GTIN)

- Defining 2012 GTIN Sunrise
- Scanner purchase and maintenance criteria
- Troublesome bar code procedures

Location Identification (GLN)

- Defining 2010 GLN Sunrise
- Defining 2010 phases for implementation

GDSN Implementation

- Defining healthcare requirements (i.e., product attributes)
- Participating in the global GDSN Implementation Initiative
- Facilitating production use of the GDSN

Current Workgroup Initiatives

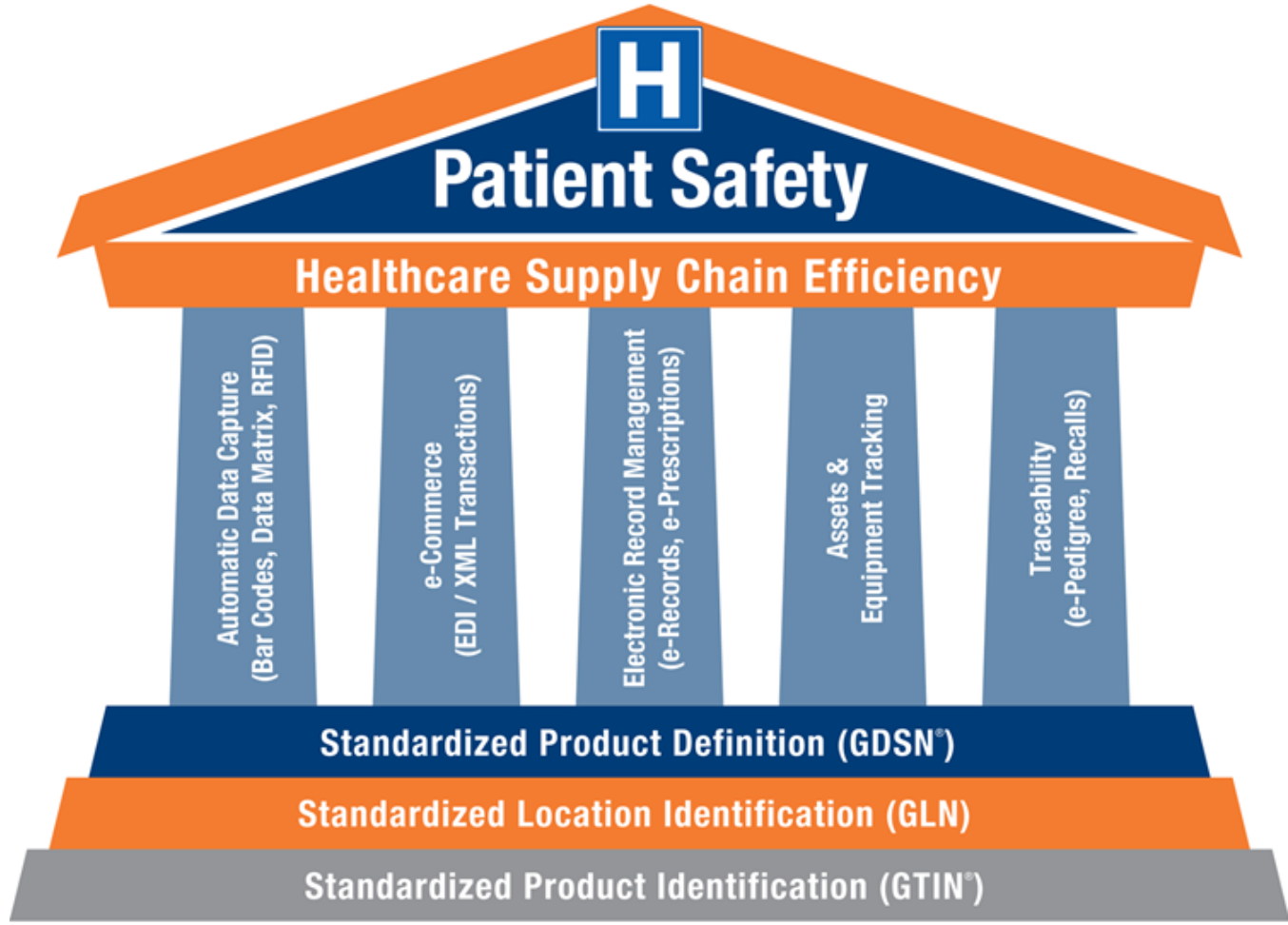
Traceability Adoption

- Developing Traceability / Visibility topic papers
- Addressing RFID Security and Privacy
- Creating usage documentation for Drug Pedigree and Traceability technologies
- Developing benefits analysis of serialized products and Traceability data
- Creating education material for industry and regulators

Application & Implementation

- Determining areas of greatest need for AIDC in hospitals
- Building an implementation guide for hospitals (GTINs, GLNs, and GDSN)
- Working with healthcare information systems providers to support the adoption of GS1 standards

“Building Patient Safety”



Standardization → Interoperability

Drive Adoption / Implementation?

- ✓ Tool Kits
- ✓ Pilots / Business cases / Training
- ✓ Solution provider outreach – identify product needs, software support, etc.
- ✓ Scorecards
- ✓ Advise U.S. regulators
- ✓ Coordinate with existing industry groups
- ✓ Implementation guidelines

ACHIEVE REAL RESULTS!

Tools & Resources

New Industry Use Cases

GLN GPO Roster Pilot Report

A GS1 Healthcare US™ Success Story:

Seton Family of Hospitals and BD Use GS1 Standards and Processes to Reduce EDI Errors in Pursuit of “Perfect Orders”

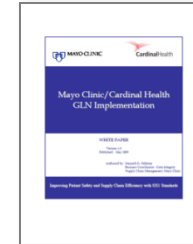
Mayo Clinic / Cardinal Health GLN Implementation White Paper

Available on the GS1 Healthcare US website at

www.gs1us.org/healthcare

Awareness Video: *Standardization...Stat*

- Developed the industry to create awareness, at all organizational levels, on the need for standards adoption and the industry-wide implementation initiative
- Available at www.gs1us.org/stat



Objectives

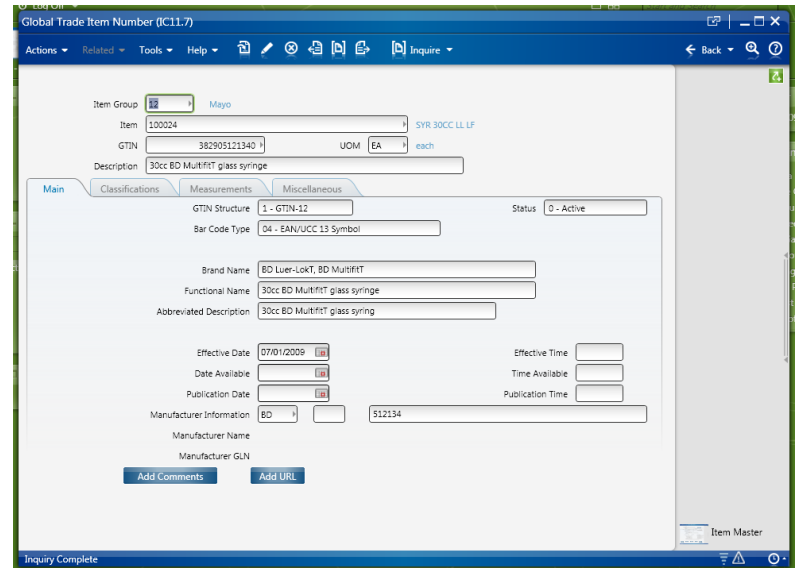
- ▶ Enhance current application release to support GS1 Standards to meet GLN and GTIN Sunrise Dates of 2010 and 2012

Current Capabilities with Lawson Applications 9.0.1.3*

- ▶ Store, Search, Transact using GLN's / GTIN's, including via EDI
- ▶ Load, Store and Use GDSN attributes
- ▶ Option to configure individual trading partners for use of GS1 Standards
- ▶ Impacted applications include Financials (AP), Procurement (RQ, IC, PO), Requisitions Self-Service and EDI for SCM

▶ ***Benefits: Help healthcare supply chain move from custom account, item and product identifiers to standardized information, reducing errors, streamlining processes and enhancing patient safety.***

**Lawson Applications 9.0.1.3, available Nov. 2009*



Improving Patient Safety and Supply Chain Efficiency with Data Standards: The Basics of GS1 Standards in Healthcare

Questions?

Feel free to email your questions to:

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Visit www.lawson.com/hcwebinars for more information on the Lawson Healthcare Webinar World Series and to find a link for this webinar recording.