Global Healthcare User Group - HUG

GS1
HUG

The global language of business

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OVERALL BENEFIT: Improving efficiency & visibility in supply and demand chains

GS1 SOLUTIONS & SERVICES USING GS1 STANDARDS
Solutions: POS / Inventory Management / Asset Management / Collaborative Planning / Traceability
Services: Global (GSMP, GEPIR, Global Registry, Training and Accreditation) & Local (e.g. Certification, Implementation, Training)

GS1 System - Integrated system of standards

GS1 BarCodes	GS1 eCom	GS1 GDSN	EPCglobal Powered by GS1
Global standards for automatic identification	Global standards for electronic business messaging	The environment for global data synchronisation	Global standards for RFID-based identification
Rapid and accurate, item, asset or location identification	Rapid, efficient & accurate business data exchange	Standardised, reliable data for effective business transactions	More accurate, immediate and cost-effective visibility of information

GS1 Identification Keys (e.g. GTIN, GLN, SSCC, GRAI, GIAI, GSRN, EPC) & Attribute Data (e.g. Best Before Date)

The global Healthcare User Group - HUG

Mission:

__Lead__ the healthcare industry to the effective utilization and development of global standards with the primary focus on ***automatic identification*** to ***improve patient safety***

Vision:

Become the ***single source*** for ***regulatory agencies*** and trade ***organizations*** (manufacturer, wholesaler, hospital and pharmacy) to seek input and direction for ***global standards*** in the healthcare industry

Guiding Principle

Collaborate Across GS1

- **HUG Members Participate on Other Work Groups within GS1 as Appropriate**
  - Provide Feedback Mechanism with Other Work Groups and GS1 Organizations that Support the Development of Auto ID or eCommerce Standards
- **Leverage Synergies with EPCglobal's HLS BAGs for Activities focusing on RFID**
  - HUG Leadership to Participate in EPCglobal Tri-Chair Monthly Meetings
- **Communicate Regulatory Activity and Communication throughout GS1**
  - RFID/EPC Discussions:
    - The HLS BAG Tri-chairs have Primary Responsibility for RFID Activities in the US via EPCglobal (Elizabeth Board)
    - HUG will include the HLS BAG Tri-chairs in Regulatory Discussions with Other Markets

HUG Organisation

Project Management Coordination
GS1 (HO, US, JP)

- - - - coordination - - - - **EPC Global**

HUG Co-chairs: R. Hollander & V. Zeinar

Membership V. Zeinar (B.Braun)	**Standards Implentation** T. Werthwine (J&J MD)	**Standards Development** P. Tomicki (Baxter)	**Business Case** E. Dzwill (J&J Ph)	**Regulatory Affairs** J. Elkin (Medtronic)	**Communic/ Coordination** J. Willmott (Smiths Med) R. Holander (Pfizer)

Membership
- identify & prioritise groups of supply chain stakeholders
- organize enlargement

Standards Implentation
- research baselines of implemented standards
- identify & help to resolve GS1 Standards implemention issues
- resolution roadmap
- action list

Standards Development
- review standards development process
- produce standards development strategy
- research industry & regulatory baseline for future healthcare standards development

Business Case
- develop business case to demon-strate the benefits of using a global standard
- best practice

Regulatory Affairs
- organize industry around a single position regarding future regulations *'speak with one global voice'*
- research baselines of legal requirements
- keep contacts to regulatory bodies

Communic/ Coordination
- lead & organize internal / external communication
- establish the **HUG** as the leading voice in the area of auto-id in HC
- web-site, press releases …

Prevention of Medical Errors

Encoding of the unit dose or unit of use package to enable automated verification to ensure right dose, for the right patient at the right time. Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

Product Authentication

Utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets.

Tracking and Tracing

Utilizing a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

Increase Total Supply Chain Efficiency

Through greater visibility, accuracy and velocity.

The Past: 1990's

- Supply Efficiencies
- Pallet Through Retail Packages

The Present: 2000-2006

- Prevention of Dispensing Errors
- Unit Dose and Unit of Use Packages

The Future: 2006 Forward

- Counterfeit Deterrence
- Pallet/Case/Retail Packages

The Past

Supply Chain Efficiencies

Early 1990's

Retail Packs –

- Wholesalers' Need for Increased Levels of Automation in their Warehousing and Distribution Facilities
- Initial Focus on Retail Packages
- National Drug Code in Barcode Format (UPC)
  - Manufacturer/Labeler, Product, and Package Size
- Code Utilized by Wholesalers, Pharmacists and FDA
- All Retail Packages by 1992

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1993 - 1996

Shipping Containers –

Healthcare Distribution Management Association (HDMA) Voluntary Standards for Barcodes

- NDC, Case Quantity, Lot Number, and Expiration Date
- Two Adjacent Panels

60 Cartons x 100 Capsules

Dilantin®
(Extended Phenytoin Sodium Capsules, USP)
100 mg
Store at controlled room temperature, 15°- 30°C (59°- 86°F).
Protect from light and moisture.

Distributed by
Pfizer Parke-Davis
Division of Pfizer Inc, NY, NY 10017
89-5965-00-3

NDC 0071-0362-40
7603
(01) 5 03 0071 0362 40 1
QTY: 60   EXP:EXPIRE   LOT:LOTNUM
(22) 8 60 3 YYMMDD LOTNUM 1

NDC 0071-0362-40
(01) 5 03 0071 0362 40 1
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Patient Safety

Dispensing Error Prevention

Patient Safety – Unit Dose and Unit of Use Packages

- March 2004: Final Rule Published
  - NDC on Unit Dose or Unit of Use Container Labels
  - Lot and Expiration Date Optional
  - Linear Symbology
  - UCC.EAN *or **HIBCC Standards***
  - ***Two*** Year Implementation

The Present: 2000-2006

Pfizer Position:

- Meet or Exceed Regulatory Requirements
- Meet Customer Needs Where Feasible
  - Utilize all Three Data Elements
    - NDC, Lot Number and Expiration Date

On Line Platen Printing

Hospital Unit Dose Blister
Reduced Space Symbology with
Composite Code

Importance of Data Standards: Structures vs. Carriers

Data Structures -

- Global Trade Identification Number
  - Enables us to use existing NDC (or JAN/EAN)
  - Identifies Package Level
    - Mitigates the Need to Change Code for Unit Dose Level
- Application Identifiers for Format
  - 01 for Global Trade Identification Number (GTIN)
  - 10 for Lot Number
  - 17 for Expiration Date
    - Addresses Individual Site Needs on Dating Formats

Importance of Data Standards: Structures vs. Carriers

Data Carriers -

- Barcodes - Linear vs. Two Dimensional
    - 2D Codes
        - More Information, Less Space
        - Improved Readability over Linear Codes
    - Laser Scanner vs. Imaging Scanner
        - Price Differential is Declining
    - FDA Requires Linear for NDC
        - OK with 2D for Lot and Expiration Date
    - Market will Drive in the End
        - Those Hospitals Wanting the Variable Info, Will Invest in the Technologies
        - Those Drug Manufacturers Wanting Improved Relations, Will evaluate how to accomplish

Patient Safety

Secure Supply Chain

Lots of Discussion About Data Elements Needed
- Product Codes - NDC/EAN/JAN
  - Prevention of Dispensing Errors
  - Inventory Management (via GTIN)
- Lot Number
  - Traceability and Recalls
- Expiration Date
  - Dispensing of Expired Medicine
  - Pharmacy Stock Rotation / Pharmacy Returns
- Serialization of Retail Packages
  - Authentication
  - Anti Counterfeiting via Track and Trace
  - Anti Diversion
    - Italian Bolino Initiative Ready for Implementation
    - Portugal, Belgium and South Africa Reviewing

All Four Data Elements are Related!

Relationship of Data Elements

Highest Level		Unlinked Codes	Lowest Level
JAN/EAN/NDC Product Identification	**Linked** **Codes** →	Lot Specific Information Lot Number and Expiration Date	Unique Retail Package Identification Mass Serialization

Linked

Codes
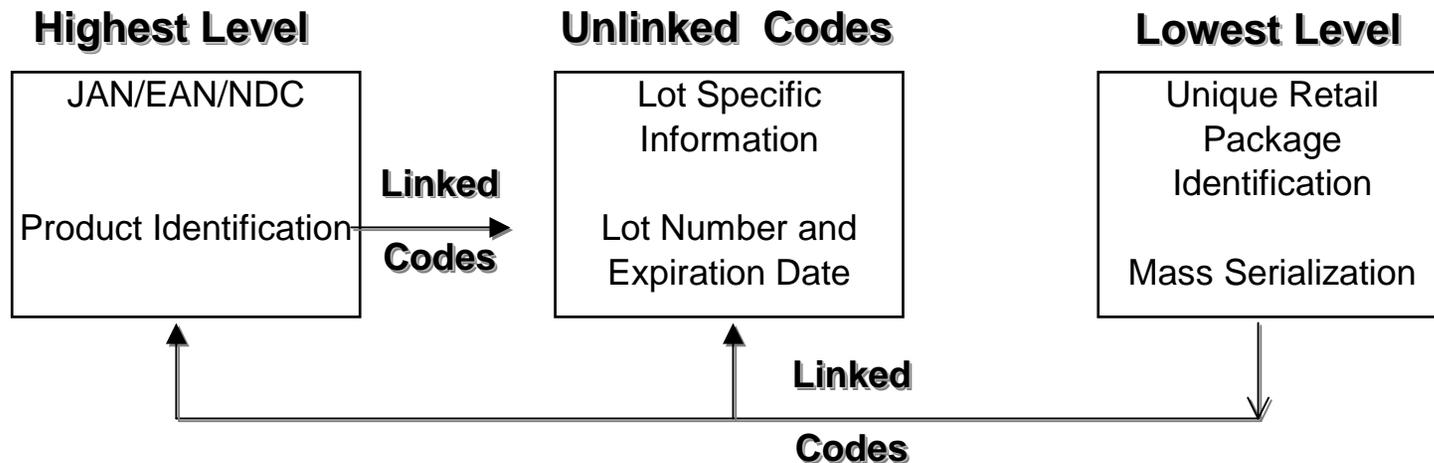
Product Code and Serial Numbers are "Pointers" to more information
- Product Name:
  - Latest Available Full Prescribing Information
  - UCC/EAN Standards Allow Linkage to Lot Specific Info
- Serial Number:
  - Lot Specific Info
    - Recall Information
    - Product Tracking and Authentication
    - Can Live on Its Own (EPC)

What has Delayed Mass Serialization?

- Pallet and Cases Possible Today via EAN.UCC Barcode Standards
- Attempts at Package Level Stalled
  - Technology
    - Barcodes Require Line of Site
    - Contradicts Term "Mass"
  - Standards
    - Proprietary Solutions => High Cost

What will Enable Mass Serialization?

- Electronic Product Code
- Radio Frequency Identification and/or 2D Barcodes
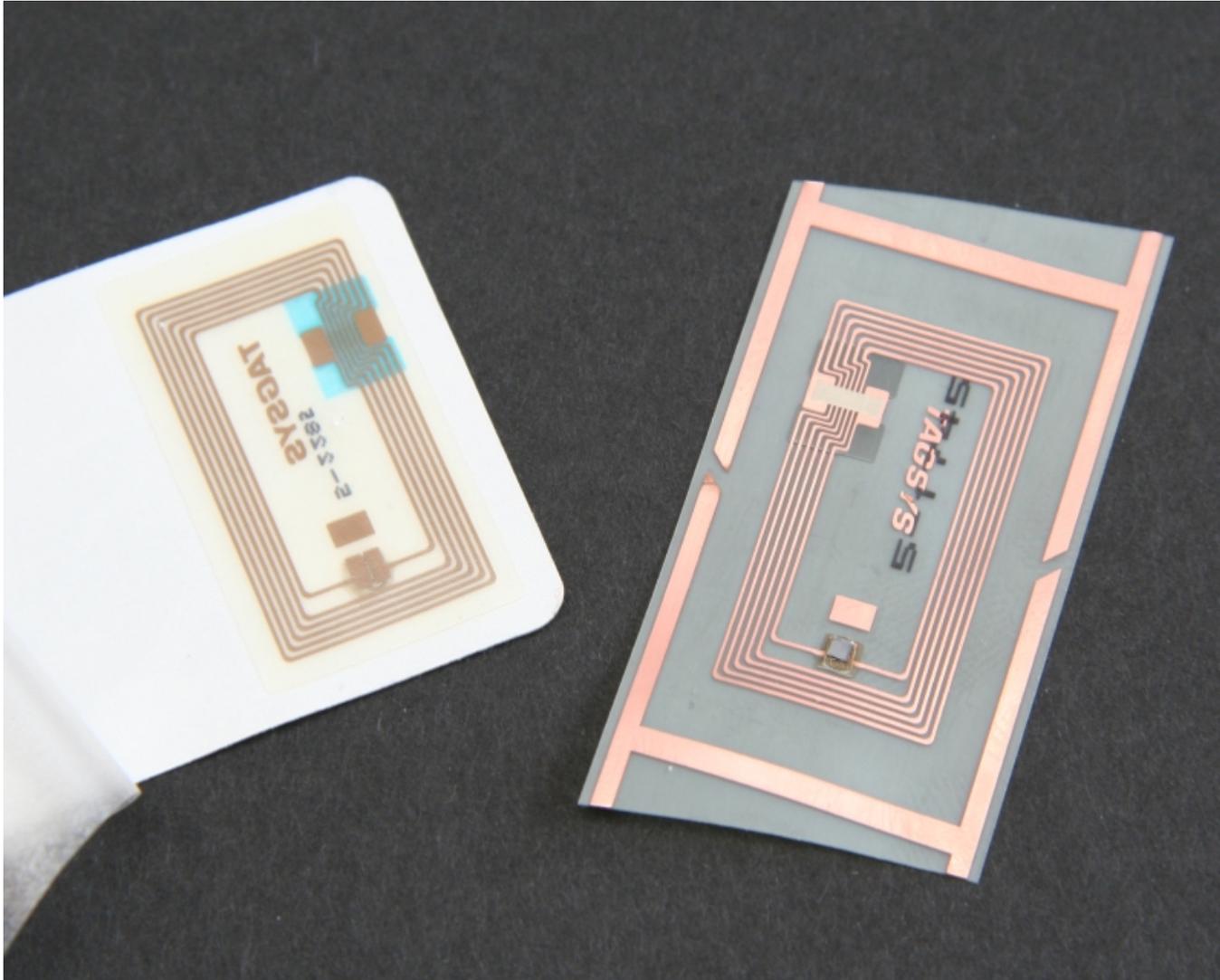
EPCglobal Logo and RFID Tag location (tag is under label)

EPC Data 2D Barcode

Color Shift

Future?

Stay Focused on Business Objective, Use and Practicality

- What role does auto-ID play in solving the objective?
  - What is the data structure required?
- What are the use requirements?
  - Granularity? Lot or Serial
  - Volume? Transactions
  - Mixed or Homogeneous Packages?
  - Line of Site or non Line of Site?
- What are the technical challenges?
  - Dosage form, Package Level and/or Package Type
  - Do we need to print the codes in-line or can we use preprinted components?
  - Practical? Technically Possible but with What Quality and Cost
- What to do?
  - Strive for Global Alignment through Global Guidelines
  - We Will Arrive There Faster