GS1’s Brand Architecture

The global language of business

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: Global standards for automatic identification
- GS1 eCom: Global standards for electronic business messaging
- GS1 GDSN: The environment for global data synchronisation
- EPCglobal: 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)
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.
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

**Membership**
V. Zeinar (B.Braun)
- identify & prioritise groups of supply chain stakeholders
- organize enlargement

**Standards Implementation**
T. Werthwine (J&J MD)
- research baselines of implemented standards
- identify & help to resolve GS1 Standards implementation issues
- resolution roadmap
- action list

**Standards Development**
P. Tomicki (Baxter)
- review standards development process
- produce standards development strategy
- research industry & regulatory baseline for future healthcare standards development

**Business Case**
E. Dzwill (J&J Ph)
- develop business case to demonstrate the benefits of using a global standard
- best practice

**Regulatory Affairs**
J. Elkin (Medtronic)
- 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**
J. Willmott (Smiths Med)
R. Holander (Pfizer)
- lead & organize internal / external communication
- establish the HUG as the leading voice in the area of auto-id in HC
- web-site, press releases …

**Project Management Coordination**
GS1 (HO, US, JP)

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

EPC Global

GS1

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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.
Tour of the Past, Present and Future

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
The Past: 1990’s

1993 - 1996
Shipping Containers – Healthcare Distribution Management Association (HDMA) Voluntary Standards for Barcodes

• NDC, Case Quantity, Lot Number, and Expiration Date
• Two Adjacent Panels
The Present

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
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
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
The Future: 2006 and Forward

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!
The Future: 2006 Forward

Relationship of Data Elements

Highest Level

JAN/EAN/NDC
Product Identification

Unlinked Codes

Lot Specific Information
Lot Number and Expiration Date

Lowest Level

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
Multi-Pronged Approach

EPCglobal Logo and RFID Tag location (tag is under label)

EPC Data 2D Barcode

Color Shift
RFID Tag or Barcode?

[Image of RFID bottle label with HF tag illustration]
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