The world of GS1 standards in healthcare

Geneva, 22 June 2010
Topics

- Background
- Where we are going
- Where we are today
- What this means to you
- Questions
Topics

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Lack of global standards...
Global standards in Retail

Over 1 million companies use global standards to manage the supply chain of consumer products.

6 billion ‘beeps’ per day.

US$ 17 billion annual cost savings in the grocery sector alone.
Global standards in Healthcare?
Global standards in Healthcare?

A manufacturing headache…
Global standards in Healthcare?

(Re-)Labeling and re-packaging by Healthcare providers...
Security, traceability and efficiency in healthcare are currently at the forefront of government regulations and industry concerns around the world.
Challenges & opportunities

1. Improving patient safety
2. Increasing supply chain efficiency
3. Ensuring regulatory compliance
The healthcare supply chain... simplified

Manufacturer

Healthcare provider

Distributor, wholesaler, GPO, ...

Patient
The healthcare supply chain ... 
in real life
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GS1 Standards in Healthcare …

Our vision

GS1 Healthcare envisions a future where the healthcare sector utilises GS1 global standards for all items, locations, people and processes to drive patient safety and supply chain efficiency improvements--starting with the manufacturer and ending with the patient.
Speak one language
across country or regional borders
between supply chain partners and
within an organisation

Sector-wide implementation of global
supply chain standards needed
Global system of standards

An integrated approach

• Standardised identification keys
  • Products, locations, assets, …
• Standardised data carriers
  • Bar codes & RFID
• Standardised sharing of static data
  • Data on products & locations
• Standardised sharing of dynamic data
  • Event data
• Standardised electronic communication

Global reach

Open standards

Proven standards

Meeting the challenges of today’s Healthcare supply chain:
patient safety, security, visibility, efficiency, accuracy, …
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The role of GS1

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

- **30 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 around the world

108 Member Organisations - 150 Countries served

Global reach, local presence
GS1 Healthcare
Global, Voluntary Healthcare User Group

To lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.
Increasing global recognition

And many more…
Working with International Organisations

World Health Organization

International Organisation for Standardization

European Committee for Standardization

Health Level 7

International Society for Blood Transfusion

International Society for Quality in Healthcare

United Nations

World Customs Organization

North Atlantic Treaty Organization

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Local Healthcare user groups driving adoption
Global work groups

- AIDC Application Standards
- Global Data Synchronisation & Product Classification
- Traceability in Healthcare
- Public Policy

Meet bi-weekly via conference call and 3 times per year in the global conferences.
GS1 Standards for Healthcare

Standards development continues, but set of global standards available to build on:

- AIDC Application Standards for 90% of medical products
- AIDC Application Standards for small instruments
- Healthcare extension in next GDSN release
- Global Traceability Standard for Healthcare
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• **What this means to you**

• Questions
How to get started

1. Contact your local **GS1 Member Organisation** for guidance

2. **Join a local user group** to work with other healthcare stakeholders to advance the sector-wide implementation of standards

3. **Join the global user group** to work with other healthcare stakeholders to develop global standards and support global harmonisation
Enabling AIDC solutions in healthcare worldwide

Chuck Biss
GS1 Global Office
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Automatic Identification and Data Capture (AIDC) refers to the methods of automatically identifying objects, collecting data about them, and entering those data directly into computer systems (i.e., without human involvement).”

Wikipedia, 2009
AIDC Application Standards

Defines the **data** to carry using specific **data carriers** for every healthcare **product** at every **packaging level**
Scope: Data

Data – a few examples:
✓ Global Trade Item Number (GTIN)
✓ Expiry Date
✓ Batch / Lot
✓ Serial Number
Scope: Data carriers

GS1-128 & GS1 DataBar

GS1 DataMatrix

EPC / RFID
Scope: All healthcare products

Pharma / Vaccine / Nutritional

Medical devices

Retail

Non-retail
Scope: All packaging levels

- Pallet
- Case / Shipper
- Secondary package
- Primary package
- Directly on the item
Scope: Risk-based solutions

AIDC Marking requirements

Minimum

Cotton balls, bandages, patient exam gloves, …

Enhanced

Catheters, needles, …

Highest

Pacemakers, hip replacements, …
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• **Where we are going**
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AIDC for Healthcare…Vision

EVERY item has ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step…
AIDC for Healthcare…Why?

- **To improve patient safety**
  - Achieve the “5 Patient Rights” or “8 Patient Rights”
  - Reduce errors
  - Ensure needed information is readily available to the healthcare practitioner
- **To increase efficiency in supply chain and treatment chain**
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Roadmap to global standards

Key standards are completed!!
Addresses ~90% of healthcare products

Others nearing completion…

- GTIN Allocation Rules
- AIDC Application Standard Phase 1 (90% of medical products)
- AIDC Application Standard Small instrument marking
- Implementation guidelines
- Location & legal entity ID
- Plasma derivatives
- Multiple bar codes
- AIDC Application Standards Phase 2 (Scope TBD)

Ratified standard | Work finalised or near closure | Work in progress or planned
GS1 General Specifications

The core standards document of the GS1 System

Now including AIDC Application Standards for Healthcare

And specific standards for marking re-usable surgical instruments

Contact your GS1 Member Organisation for your copy!
AIDC Implementation Guide

How to implement all aspects of the new Healthcare AIDC additions and changes to the GS1 General Specifications

Coming soon!!
## AIDC Application Standards for Healthcare and Product Marking Grid

### Minimum Level of AIDC Marking (Retail)

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Description</th>
<th>Marking Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>DPM: 1 pill</td>
<td>Primary Package: 1 pill in blisterpack of 12 pills</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>DPM: 1 pill</td>
<td>Primary Package: 1 pill in blisterpack of 12 pills</td>
</tr>
</tbody>
</table>

### Minimum Level of AIDC Marking (Non-Retail)

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Description</th>
<th>Marking Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>DPM: 1 empty syringe</td>
<td>Primary Package: 1 empty syringe in blisterpack</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>DPM: 1 empty syringe</td>
<td>Primary Package: 1 empty syringe in blisterpack</td>
</tr>
</tbody>
</table>

### Enhanced Level of AIDC Marking

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Description</th>
<th>Marking Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>DPM: 1 contact lens</td>
<td>Primary Package: 1 contact lens in vial</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>DPM: 1 contact lens</td>
<td>Primary Package: 1 contact lens in vial</td>
</tr>
</tbody>
</table>

### Highest Level of AIDC Marking

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Description</th>
<th>Marking Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>DPM: 1 reusable scalpel handle</td>
<td>Primary Package: 1 reusable scalpel handle in pouch</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>DPM: 1 reusable scalpel handle</td>
<td>Primary Package: 1 reusable scalpel handle in pouch</td>
</tr>
</tbody>
</table>

### Direct Part Mark (AIDC marked directly onto a single, unpackaged unlabeled item)

- No marking

### Primary Package (AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of a single item, or a group of items for a single therapy such as a kit)

- No marking

### Secondary Packaging (AIDC marked onto the next level of packaging, containing one or more single items in their Primary Packaging)

- GTIN

### Case/Shipper (AIDC marked onto a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging)

- GTIN

### Pallet (AIDC marked onto a pallet. May contain one or more cases/shipments)

- GTIN
The foundation of the GS1 System

GS1 Identification Keys

Provide access to information held in computer files – Information about company/location, package, product, price, etc.

1234567891234
GS1 Identification Keys

- **Item identifier** = GTIN
  Global Trade Item Number

- **Logistics unit identifier** = SSCC
  Serial Shipping Container Code

- **Location identifier** = GLN
  Global Location Number

- Unique
- Non-significant
- International
- Secure
- Foundational

And there are more …
GS1 Identification Keys

**GTIN** = Global Trade Item Number
*Products or Services*

**SSCC** = Serial Shipping Container Codes
*Individual Logistics Units*

**GLN** = Global Location Numbers
*Physical Locations and Legal Entities*

**GRAI** = Global Returnable Asset Identifier
*Returnable Assets*

**GIAI** = Global Individual Asset Identifier
*Fixed Assets*

**GSRN** = Global Service Relation Number
*Recipient of services*

**GSIN** = Global Shipment Identification Number*
*Multiple Logistic Units for Trade (Shipper Assigned)*

**GINC** = Global Identification Number for Consignment*
*Multiple Logistic Units for Transport (Transport Company Assigned)*

**GDTI** = Global Document Type Identifier
*Document Type*

*Not identified in General Specifications as ID key for healthcare*
# GS1 Application Identifiers

## Key attributes

GS1 General Specifications includes complete list of 100+ GS1 Application Identifiers

### Application Identifiers for healthcare use:

<table>
<thead>
<tr>
<th>Code</th>
<th>Identifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>SSCC (Serial Shipping Container Code)</td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>GTIN (Global Trade Item Number)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Lot / Batch</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Expiry Date</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Serial Number</td>
<td></td>
</tr>
<tr>
<td>7003</td>
<td>Expiry Date + Time</td>
<td></td>
</tr>
<tr>
<td>7004</td>
<td>Active Potency</td>
<td></td>
</tr>
<tr>
<td>8003</td>
<td>GRAI (Global Returnable Assets Identifier)</td>
<td></td>
</tr>
<tr>
<td>8004</td>
<td>GIAI (Global Individual Assets Identifier)</td>
<td></td>
</tr>
</tbody>
</table>
GS1 Data Carriers

**Bar Codes**
- Affordable & easy implementations
- Pervasive technology
- Extensive standardization
- Proven applications / ROI’s
- Adaptability / flexibility
- Expandable data capacity
- Visibility into the movement of physical objects in the supply chain

**RFID**
- Non-line of sight
- Range
- Bulk read - Speed
- Zero Human Involvement Operations
- Durability
- Read/Write
- Visibility into the movement of physical objects in the supply chain at new levels

**Automation**
Integration of physical and computer worlds
Basic bar code system
GS1 BarCodes for Healthcare

EAN/UPC

GS1 DataBar

GS1-128

Composite Component

GS1 DataMatrix

ITF-14
GS1 Data Carriers for Healthcare

Camera-based bar code scanners are needed in HC !!

GS1 DataMatrix

GS1-128 & GS1 DataBar
GS1 Data Carriers

Basic RFID system

Host  Reader Module  Antenna  Tag
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ONE global standard for AIDC in healthcare now available

Many countries have already adopted GS1 Standards
We anticipate many more…
Putting the standards to work…
1. Contact your local **GS1 Member Organisation** for guidance

2. **Get familiar** with the standards / guidelines
   - Attend breakout sessions this week!
   - Participate on GS1 implementation projects / team

3. **Do a gap analysis**…your items vs. GS1 Standards
   - Focus on key items and facilities…don’t ‘boil the ocean’
   - Build action plans, budgets, management approval

4. Implement your **action plan**
   - Start small, conduct Pilot Projects, “learn by doing”, “crawl before you walk / run”…
AIDC sessions this week

This Week:

• Wednesday, 11:15 – 12:45  (breakout sessions)
  Roundtable discussion groups
  • First steps for AIDC product marking - Manufacturers focus
  • First steps for AIDC product marking - Providers focus

• Wednesday, 14:00 – 15:30  (breakout session)
  Roundtable discussion group
  • Defining the next steps for AIDC in Healthcare identification and marking - Healthcare AIDC Phase 2

• Thursday, 11:15 – 12:45 (breakout session)
  Roundtable discussion group
  • Implementing Global Location Numbers (GLN) and the role of the GLN registries
Global teams
• Implementation Guideline
• Blood / Plasma Derivatives
• Location and Legal Entity ID
• Patient and Caregiver ID
• Multiple Barcodes
• Barcode / EPC Interoperability
• Serialization
• Phase 2: AIDC Application Standards

Local teams
• Contact your local Member Organisation representative
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Making electronic product catalogues through a single point-of-entry a reality

Peter Alvarez
GS1 Global Office
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Managing master data

Critical business processes require reliable product and location data:

- Distribution systems
- Inventory replenishment
- Billing/accounts payable
- Traceability systems (pedigree systems, adverse event reporting, product recalls, barcode point-of-care systems, …)

Inaccurate or bad data add cost and risk
Managing master data today

Product catalogues - current situation:

• **Varying methods of communicating new items**
  - Supplier A - printed catalog
  - Supplier B – price quote
  - Supplier C – PDF data
  - Supplier D – Excel tables
  - Supplier E – text data
  - Supplier F – link to website

• **Varying methods of communicating updates/changes (or not communicating)**

• **Varying descriptions and levels of detail (product attributes)**
No standardised product ID

Different products – same number

For example:
Part Number 10313 in Premier Inc. Product Item Master 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"

* Source: US DoD Study
No standardised product information

Inconsistent packaging data

• Order 20 cases, receive 20 boxes
• No uniform Unit of Measure standard
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOUTHLAND TECHNOLOGY 3M</td>
<td>3M 800-327-5360</td>
</tr>
<tr>
<td>3M CO PHOTO PRODUCTS DIV</td>
<td>3M CG</td>
</tr>
<tr>
<td>3M DIAGNOSTIC SYSTEMS INC</td>
<td>3M DENTAL 800-237-1850</td>
</tr>
<tr>
<td>3M ELECTRICAL SPECIALTIES DIV</td>
<td>3M ESPE DENTAL DIVISION 800-364-3577</td>
</tr>
<tr>
<td>3M HEALTH</td>
<td>3M ESPE UNITED STATES</td>
</tr>
<tr>
<td>3M HEALTH CARE CDI</td>
<td>3M ESPE</td>
</tr>
<tr>
<td>3M HEARING COMPONENTS</td>
<td>3M HEALTH CARE 800-521-2818</td>
</tr>
<tr>
<td>3M INDUSTRIAL TAPES LTD</td>
<td>3M HEALTHCARE PRODUCT</td>
</tr>
<tr>
<td>3M MEDICAL DEVICE DIV</td>
<td>3M HEALTHCARE</td>
</tr>
<tr>
<td>3M MEDICAL IMAGING SYSTEMS DIV</td>
<td>3M MEDSURGE</td>
</tr>
<tr>
<td>3M MEDICAL PRODUCTS DIV</td>
<td>3M MINNESOTA MINING MFG. OFFICE</td>
</tr>
<tr>
<td>3M MEDICAL-SURGICAL DIV</td>
<td>3M MINNESOTA MINING &amp; MFG. CO.</td>
</tr>
<tr>
<td>3M MEDICALСУРG</td>
<td>3M OCC. HEALTH AND ENV. SAFETY DIV.</td>
</tr>
<tr>
<td>3M PHARMACEUTICALS AND MEDICAL S</td>
<td>3M OCC. HEALTH AND ENV. SAFETY DIV.</td>
</tr>
<tr>
<td>3M MEDICALСУРGICAL</td>
<td>3M SANСУРG</td>
</tr>
<tr>
<td>3M OCCUPATIONAL AND SAFETY DIV</td>
<td>3M SURGICAL</td>
</tr>
<tr>
<td>3M MINNESOTA MINING &amp; CO</td>
<td>3M UNITEK 800-423-4568</td>
</tr>
<tr>
<td>C0</td>
<td>3M UNITEK</td>
</tr>
<tr>
<td>3M FEDERAL GOVERNMENT</td>
<td>THREE M ESPE</td>
</tr>
<tr>
<td>3M FEDERAL SYSTEMS DEPARTMENT</td>
<td>3M COMPANY CO WAHL CORP.</td>
</tr>
<tr>
<td>3M HEALTH CARE SYSTEM</td>
<td>MINNESOTA SCIENTIFIC</td>
</tr>
<tr>
<td>3M HEALTHCARE $250 MINIMUM ORDER</td>
<td>CORPORATE ALLIANCE 3M CUSTOMER SERV</td>
</tr>
<tr>
<td>3M HEALTHCARE(MINNESOTA MINING)</td>
<td>3 M HEALTHCARE</td>
</tr>
<tr>
<td>3M MEDICAL - CREDIT CARD</td>
<td>3 M UNITEK CORP</td>
</tr>
<tr>
<td>3M MEDICAL PRODUCTS</td>
<td>3 M</td>
</tr>
<tr>
<td>3M OCC. HEALTH AND ENV. SAFETY DIV</td>
<td>3-M COMPANY</td>
</tr>
<tr>
<td>3M OCCUPATIONAL AND SAFETY DIV</td>
<td>3-M COMPANY:CO 0</td>
</tr>
<tr>
<td>3M SAFETY DIVISION</td>
<td>3-M COMPANY:CO OEM PRODUCTS</td>
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<tr>
<td>3M-DENTAL PRODUCTS DIVISION</td>
<td>3-M PHARMACEUTICALS</td>
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<td>3M HEALTH CARE</td>
<td>33M HEALTHCARE</td>
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<td>3M DENTAL PRODUCTS DIV</td>
<td>3M</td>
</tr>
<tr>
<td>3M UNITEK CORPORATION</td>
<td>3M PUERTO RICO</td>
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<tr>
<td>3M UNITEK DENTAL PRODUCTS</td>
<td>3M SPECIALITY CHEMICAL</td>
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<tr>
<td>3M BIOLOGICAL</td>
<td>3M &amp; SAN-MAR</td>
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<tr>
<td>3M ESPE DENTAL PRODUCTS</td>
<td>3M CRJ7242</td>
</tr>
<tr>
<td>3M HEALTH CARE (MEDISURG PRODS)</td>
<td>3M MINNESOTA MI</td>
</tr>
<tr>
<td>3M CO CHECKPOINT METO</td>
<td>3M MINNESOTA MINING &amp; MFG. CO</td>
</tr>
</tbody>
</table>

No standardised location ID

Multiple manufacturer names

Order with whom?
## Data errors in healthcare

<table>
<thead>
<tr>
<th>Data error</th>
<th>% of total</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>GPO</th>
<th>Healthcare provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Middle Levels of Packaging</td>
<td>15-20%</td>
<td>1-4%</td>
<td>20-25%</td>
<td>15-25%</td>
<td></td>
</tr>
<tr>
<td>Hard “Packaging Quantity” Errors</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2-5%</td>
<td></td>
</tr>
<tr>
<td>Unit of Measure Confusion/Misuse</td>
<td>2-6%</td>
<td>1-3%</td>
<td>2-5%</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Missing Packaging—not Middle Level</td>
<td>3-8%</td>
<td>3-8%</td>
<td>3-7%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Name Problems</td>
<td>NA</td>
<td>2-5%</td>
<td>1-4%</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>Obsolete Products</td>
<td>1-4%</td>
<td>2-5%</td>
<td>1-8%</td>
<td>5-15%</td>
<td></td>
</tr>
<tr>
<td>Missing Product Brand Names</td>
<td>2-5%</td>
<td>5-10%</td>
<td>5-10%</td>
<td>20-25%</td>
<td></td>
</tr>
<tr>
<td>Incomplete Item Descriptions</td>
<td>5-15%</td>
<td>3-12%</td>
<td>5-15%</td>
<td>10-20%</td>
<td></td>
</tr>
<tr>
<td>Wrong Customer Unit Prices</td>
<td>Unknown</td>
<td>1-2%</td>
<td>NA</td>
<td>1-2%</td>
<td></td>
</tr>
<tr>
<td>Customer Paid More Than Lowest Contract Price</td>
<td>NA</td>
<td>Unknown</td>
<td>NA</td>
<td>3-6%</td>
<td></td>
</tr>
</tbody>
</table>

Source: US Department of Defense Study
Bad data add cost and risk

• Inaccurate and inconsistent data in the Healthcare supply chain add billions of $, €, … in costs
  • Supply chain information inefficiencies
  • Inaccurate data in transactions
  • Purchase orders and invoices with errors
  • Manual work-around processes to correct errors

• Inaccurate and inconsistent data add risk to patient safety
  • Disruptions may result in the inavailability of products to treat a patient
  • Medication errors due to incorrect relabeling
For reference:
Data errors in Retail...
A few examples

**Dimensions mis-match**
- 4 retailers: 99.8%
- 2 retailers: 54%

**Weight mis-match**
- 4 retailers: 99.8%
- 2 retailers: 60%

Retailer data mis-match with suppliers:
- Product dimensions: 80%
- Trade pack dimensions: 69%
Managing master data tomorrow

Supplier = data source

Needs single point-of-entry
• One database to load new item data and update data on existing items

Needs security
• Authorisation access by supply chain partners

Standards-based
• Standard identification keys
• Predefined (set of) product attributes

Hospital = data recipient

Needs single point-of-truth
• One source for up-to-date, accurate data
• Continuous synchronisation

Standards-based
• Standard identification keys
• Consistently formatted information
• Complete information
Global Data Synchronisation

- Supply side:
  - Manufacturer

- GDSN:
  - Data Pool
  - GS1 Global Registry
  - Data Pool

- Demand side:
  - Distributor
  - Provider
  - Retail pharmacy
  - GPO

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GDSN data exchanges
How GDSN works

1. **Load data**
   - The seller registers product and company information in its data pool

2. **Register data**
   - A small subset of this data is sent to the GS1 Global Registry

3. **Request subscription**
   - The buyer, through its own data pool, subscribes to receive a seller's information

4. **Publish data**
   - The seller’s data pool publishes the requested information to the buyer’s data pool

5. **Confirm & inform**
   - The buyer sends a confirmation to the seller via each company's data pool, which informs the seller of the action taken by the buyer using the information
GDSN data attributes

25 mandatory attributes
- 8 mandatory attributes required to register products in the GS1 Global Registry
- 17 mandatory attributes to operate in the GDSN

200+ optional attributes
- Trading partners decide whether to exchange additional information
- There are currently 203 optional GDSN attributes which support healthcare specific needs
- 33 new data requirements are being added to the GDSN standard
Topics

• Background

• **Where we are going**

• Where we are today

• What this means to you

• Questions
G DSM N for Healthcare…Vision

All product information for every item is current, correct, and available via a single globally-accessible network.
Topics

• Background
• Where we are going
• Where we are today
• What this means to you
• Questions
Roadmap to global standards

Data Synchronisation & Product Classification for Healthcare

- Global Pilot
- Business Requirements
- Solution Design
- Healthcare GDSN Extension
- GDSN Global Deployment Initiative – Etoile Healthcare
- Update Inventory
- Requirements Matrix
- Recommendation Long Term Classification
- GPC codes released
- Implementation Support

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Version 1.12 – January 2010

GS1 GDSN
Global Data Synchronisation Network

On boarding partner
Manufacturer
Distributor/Wholesaler/GPO
Healthcare provider
Results 2007 DoD Pilot

• **Opportunities identified to save costs**
  • Better contract price available
  • Saved $18.7M so far at 30+ hospitals

• **Opportunities identified to increase DoD eCommerce**
  • Moved $7.766M to eCommerce services

• **Created robust DoD & VA Med Surg product data bank of 1 million + records**
  • Accurate master records for 93% ($407M) of DoD buys
  • Joint DoD & VA access to pricing, packaging, product ID

• **Created active collaboration with Healthcare Industry**
  • Ongoing pilots with manufacturers and PV distributors
  • PDU as goal within Healthcare Standards Organizations
Global GDSN Pilot (2008)
Results 2008 Global GDSN Pilot

Demonstrated that the GDSN works across international boundaries

- Interoperability among data pools
- The technology works in various settings

Report available at www.gs1.org/healthcare
A global implementation initiative to use the GDSN’s unique position to meet current and emerging requirements for electronic product catalogue data, including pending regulatory demands and commercial needs for reliable product data between healthcare trading partners.
40 GDSN implementation attributes for healthcare

Global Trade Item Number (GTIN)  Invoice Unit Y/N
Pack Level  Shipping Unit Y/N
Manufacturer Part Number  Base Unit Y/N
Hierarchy (Parent GTIN)  Variable Unit Y/N
Hierarchy (Child GTIN)  Returnable Package Y/N
Hierarchy (Quantity of Children)  Marked with Lot Number Y/N
Publisher Global Location Number (GLN)  Bar code Type
Target Market  GPC code
Brand Owner and GLN  Optional Classification Agency
Manufacturer Name and GLN  Optional Classification Agency Value
Functional Name  Start Date
Brand Name  Effective Date
Description  Shelf Life From Production
Height + Unit of Measure  Shelf Life From Delivery
Width + Unit of Measure  Contains Blood
Depth + Unit of Measure  Implantable
Gross Weight + Unit of Measure  Contents of Concern
Net Content + Unit of Measure  Reusability Types
Consumer Unit Y/N  Brand or Generic Flag
Orderable Unit Y/N  Does Product Contain Latex
Global GDSN Implementation Initiative for Healthcare

- Launched June 2009
- Today:
  - Participation: 26 healthcare organisations
  - Connections: 57 live
  - Finalised Phase 2 report: sharing lessons learned
- Next step:
  - Expansion to more countries and more participants
Topics

• Background
• Where we are going
• Where we are today
• What this means to you
• Questions
ONE global standard for data synchronisation in healthcare
Putting the standards to work...
Goal: Single global source of truth for product data

1. Subscribe to a GDSN-certified Data Pool
2. Identify trading partners and products
3. Register supplier and products
4. Subscription to supplier and products
5. Start data synchronisation
6. Measure success and expand
7. Use data for transactions
GDSN session this week

This Week:

• Wednesday, 14:00 – 15:30 (breakout session)
  Roundtable discussion groups
  • Electronic product catalogues, UDI databases and the GDSN:
    Making it work
Join us!!!

Global teams
• Global GDSN Implementation Initiative

Local teams
• Contact your local Member Organisation representative or a GDSN-certified data pool
Topics

• Background

• Where we are going

• Where we are today

• What this means to you

• Questions
Global standards to achieve end-to-end traceability

Janice Kite
GS1 Global Office
Topics

• Background

• Where we are going

• Where we are today

• What this means to you

• Questions
Topics

- Background
- Where we are going
- Where we are today
- What this means to you
- Questions
Traceability is the ability to **track forward** the movement through specified stage(s) of the extended supply chain and **trace backward** the history, application or location of that which is under consideration.

*GS1 GTSH Issue 1.0.0, Feb-2009*
Develop a suite of standards to enable traceability of healthcare products from point of production to point of use.
Traceability matters because of...

... regulatory compliance
... anti-counterfeiting/diversion
... product recalls
... adverse event reporting and post-market surveillance
... medical error reduction
... documenting medical product use in Electronic Health Records (EHR) and Hospital Information Systems (HIS)
... efficient logistics management
Traceability is currently at the forefront of government regulations and industry concerns around the world…

A few examples:

**FDA Amendments Act of 2007**
- Authority to develop regulations establishing a Serialised Numerical Identifiers (SNI) system for drugs
- Authority to develop regulations establishing a Unique Device Identification (UDI) system for medical devices

**“Pharma Package”** - Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector

**Recast of Medical Device Directive** - To establish a UDI System
Brazil - Law 11.903/2009 - To establish a national drug traceability and authentication system

Colombia - Decree 4725/2005 - To establish a national traceability system

Turkey – To establish a national traceability system for drugs and medical devices using DataMatrix

China – Shanghai Regulation 7 November 2006 – established a traceability system for implantable medical devices in 2007

And many more…
Topics

• Background

• Where we are going

• Where we are today

• What this means to you

• Questions
GS1 Vision for Traceability in Healthcare

Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production\(^1\) to Point of Use\(^2\)

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Lot/Batch No. Al(10)), if applicable, at point of production
- Identification remains with/on the item throughout its intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Keys** (e.g. GLN) across the entire supply chain
- All **patients and care givers**, when in a care giving environment, are identified with the appropriate GS1 identification Keys
- Agreed **master data** is captured and shared (e.g. via GDSN) on demand amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) on demand amongst traceability stakeholders

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1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)...
2. The terms use or used can also mean consumed, infused, implanted, destroyed
GS1 Vision for Traceability in Healthcare

Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production\(^1\) to Point of Use\(^2\)

SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time on demand
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time on demand
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

1. The terms production or producer can also mean commercially available, manufacture\(r\), creation\(or\), compounding\(er\)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
Traceability across the supply chain
Topics

• Background

• Where we are going

• Where we are today

• What this means to you

• Questions
Roadmap to Global Standards

Global Traceability Standards for Healthcare

- GTSH V.1
- Traceability in Healthcare II (TH-II)
  - Use Cases
  - Business Requirements
    - Visibility Stds - Gap analysis
    - eCom Stds - Gap analysis
    - CR(s)
  - Active participation in GSMP work groups
    - Migration Plan / Maturity Matrix
    - Conformance Checklist
    - GTCH Audit
- GTSH IG V2

Ratified standard
Work finalised or near closure
Work in progress or planned
Global Traceability Standard for Healthcare

Business process and system requirements for supply chain traceability

Published 27 February 2009

Available at www.gs1.org
GTSH Implementation Guide

To assist stakeholders to implement a traceability system in line with the GTSH utilising the GS1 System of Standards

Published 24 April 2009

Available at www.gs1.org
Traceability – a business process

Global Traceability Standard for Healthcare (GTSH)

A Process Standard enabled by the GS1 System of Standards
And GTSH Implementation Guideline
Core components of Traceability

✓ **Unique identification**
  • Global product identification number
  • Lot/batch number or serial number (unique number at the unit level)

✓ **Data capture**
  • Bar coding or radio frequency identification (RFID)

✓ **Links management**
  • Managing identification from point of production to point of use

✓ **Data communication**
  • Associate the physical flow of products with the information flow
  • Different information sharing models
Information Sharing Model 1

One up, one down

- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor
Distribution Information Sources

Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism.
Global Traceability Standard for Healthcare (GTSH)

**A Process Standard** enabled by the GS1 System of Standards
And GTSH Implementation Guideline
Traceability in Healthcare II (TH-II)

- Focus on EPCglobal and eCOM areas:

- Identified, prioritised and drafting **Core Use Cases (Sub-Teams):**
  1. Chain of Custody
  2. Chain of Ownership
  3. Product Identifier Authentication
  4. Product Recall

Combined. Business Requirements gathered
Topics

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• Questions
ONE global process standard for traceability in healthcare now available

A suite of global standards to enable traceability in healthcare available in 2011
Putting the standards to work…
How YOU can get started

1. Contact your local **GS1 Member Organisation** for guidance

2. Get **familiar** with the standards / guidelines
   - Attend breakout session this week!
   - Participate on GS1 implementation projects / team

3. Do a **gap analysis** vs. GS1 Standards
   - Focus on key items and facilities...don’t ‘boil the ocean’
   - Build action plans, budgets, management approval

4. Implement your **action plan**
   - Start small, conduct Pilot Projects, “learn by doing”, “crawl before you walk / run”...
Traceability session this week

This Week:

- Thursday, 11:15 – 12:45 (breakout session)
  Roundtable discussion groups
  - Traceability in Healthcare: Which model?
Join us!!!

Global teams
• Global TH-II Team - Product Identifier Authentication

Local teams
• Contact your local Member Organisation representative
Topics

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