The world of GS1 standards in healthcare
Singapore, 9 November 2010
Agenda

• General introduction – Jan Denecker
• Automatic Identification & Data Capture – Chuck Biss
• Global Data Synchronisation – Peter Alvarez
• Traceability in Healthcare – Janice Kite
Topics

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

• Background
• Where we are going
• Where we are today
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Lack of global standards...
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

Distributor, wholesaler, GPO, ...

Healthcare provider

Patient
The healthcare supply chain ... *in real life*

- Manufacturer
- Distributors/Wholesalers
- Internet
- Consumer
- Retail
- Healthcare provider
- Patient
- Transporter providers
- Counterfeiter
Topics

• Background

• Where we are going

• Where we are today

• What this means to you
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.
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

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

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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
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.
Leading healthcare organisations pave the way...

Corporate members of the global user group
Leading healthcare organisations pave the way…

Healthcare providers and Group Purchasing Organisations going global

France
- Comparatio Health GmbH
- Erasmus MC
- HUG
- Hospital Authority

Germany
- France
- Netherlands
- Switzerland

Netherlands
- Hong Kong
- Novation
- Orthopädisches Spital Wien-Spising
- Premier

USA
- Austria
- Ireland
- Netherlands
- France
- USA
- USA

© 2010 GS1
Increasing global recognition

And many more...
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
- GTIN Allocation Rules for Healthcare
- Guideline for plasma derivatives
Topics

• Background
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• Where we are today
• What this means to you
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
Topics

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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

Retail

Medical devices

Non-retail
Scope: All packaging levels

- Pallet
- Case / Shipper
- Secondary package
- Primary package
- Directly on the item
Scope: Solutions based on information needs

Minimum
Cotton balls, bandages, patient exam gloves, …

Enhanced
Catheters, needles, …

Highest
Pacemakers, hip replacements, …

AIDC Marking requirements
Topics

• Background

• **Where we are going**

• Where we are today

• What this means to you
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**
Topics

• Background
• Where we are going
  • Where we are today
• What this means to you
AIDC Application Standards for Healthcare

Roadmap to global standards

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)
- **Pharmaceuticals:** Distributed and/or sold primarily via retail channels
- **Medical Devices:** Distributed and/or sold primarily via retail channels

<table>
<thead>
<tr>
<th>Description of Example Product Hierarchy</th>
<th>Direct Part Mark (AIDC marked directly onto a single, unpackaged, unlabeled item)</th>
<th>Primary Package (AIDC marked on the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of single item, or a group of items for a single therapy such as a kit.)</th>
<th>Secondary Packaging (AIDC marked on the next level of packaging, containing one or more single items in their Primary Packaging.)</th>
<th>Case / Shipment (AIDC marked on a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging.)</th>
<th>Pallet (AIDC marked onto a pallet. May contain one or more Case / Shipments.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPM: 1 pill Primary Package: 1 pill in blister pack of 12 pills</td>
<td>DPM: 1 pill Primary Package: 1 pill in pouch</td>
<td>DPM: 1 pill Primary Package: 1 empty syringe in blister pack of 12 pills</td>
<td>DPM: 1 contact lens Primary Package: 1 contact lens w/ in MSL</td>
<td>DPM: 1 contact lens Primary Package: 1 contact lens w/ in MSL</td>
<td>DPM: 1 contact lens Primary Package: 1 contact lens w/ in MSL</td>
</tr>
<tr>
<td>Secondary Package: 3 blister packs of 36 pills in one carton</td>
<td>Secondary Package: 12 pouch sets of 36 pills in one carton</td>
<td>Secondary Package: 2 empty blister packs of 12 pills in one carton</td>
<td>Secondary Package: 12 cartons (144 contacts)</td>
<td>Secondary Package: 12 cartons (144 contacts)</td>
<td>Secondary Package: 12 cartons (144 contacts)</td>
</tr>
<tr>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
</tr>
<tr>
<td>Pallet: 200 cases (172,800 pills)</td>
<td>Pallet: 200 cases (172,800 pills)</td>
<td>Pallet: 200 cases (172,800 pills)</td>
<td>Pallet: 100 cases (4000 lenses)</td>
<td>Pallet: 100 cases (4000 lenses)</td>
<td>Pallet: 100 cases (4000 lenses)</td>
</tr>
</tbody>
</table>

## Minimum Level of AIDC Marking (Non-Retail)
- **Pharmaceuticals:** Distributed and/or sold primarily via non-retail channels
- **Medical Devices:** Distributed and/or sold primarily via non-retail channels

<table>
<thead>
<tr>
<th>Description of Example Product Hierarchy</th>
<th>Direct Part Mark (AIDC marked directly onto a single, unpackaged, unlabeled item)</th>
<th>Primary Package (AIDC marked on the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of single item, or a group of items for a single therapy such as a kit.)</th>
<th>Secondary Packaging (AIDC marked on the next level of packaging, containing one or more single items in their Primary Packaging.)</th>
<th>Case / Shipment (AIDC marked on a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging.)</th>
<th>Pallet (AIDC marked onto a pallet. May contain one or more Case / Shipments.)</th>
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<tr>
<td>DPM: 1 pill Primary Package: 1 pill in blister pack of 12 pills</td>
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<td>DPM: 1 pill Primary Package: 1 empty syringe in blister pack of 12 pills</td>
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<td>Secondary Package: 3 blister packs of 36 pills in one carton</td>
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<td>Secondary Package: 12 cartons (144 contacts)</td>
<td>Secondary Package: 12 cartons (144 contacts)</td>
</tr>
<tr>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (864 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
<td>Case: 24 cartons (172800 pills)</td>
</tr>
<tr>
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<td>Pallet: 100 cases (4000 lenses)</td>
<td>Pallet: 100 cases (4000 lenses)</td>
<td>Pallet: 100 cases (4000 lenses)</td>
</tr>
</tbody>
</table>

## Enhanced Level of AIDC Marking
- **Pharmaceuticals:** Distributed and/or sold primarily via retail channels
- **Medical Devices:** Distributed and/or sold primarily via retail channels

## Highest Level of AIDC Marking
- **Pharmaceuticals:** Distributed and/or sold primarily via non-retail channels
- **Medical Devices:** Distributed and/or sold primarily via non-retail channels

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Note: The image contains a table and a grid that outlines the AIDC Application Standards for Healthcare and Product Marking Grid. The table details the marking requirements for pharmaceuticals and medical devices at different levels of AIDC marking, including minimum marking requirements, direct part marking, primary package marking, secondary packaging marking, and case/shipper marking. The grid visually represents these requirements with icons and text descriptions.
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</td>
<td>Serial Shipping Container Code</td>
</tr>
<tr>
<td>01</td>
<td>GTIN</td>
<td>Global Trade Item Number</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</td>
<td>Global Returnable Assets Identifier</td>
</tr>
<tr>
<td>8004</td>
<td>GIAI</td>
<td>Global Individual Assets Identifier</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
GS1 Data Carriers

Basic bar code system

Host  Scanner / Reader Module  Bar Code Label / Mark
GS1 BarCodes for Healthcare

- EAN/UPC
- GS1 DataBar
- GS1-128
- GS1 DataMatrix
- ITF-14
Camera-based bar code scanners are needed in HC!!

GS1 Data Carriers for Healthcare

GS1-128 & GS1 DataBar

GS1 DataMatrix
GS1 Data Carriers

Basic RFID system

Host  Reader Module  Antenna  Tag
Topics

• Background
• Where we are going
• Where we are today
• What this means to you
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, 11:00 – 12:30  (breakout session)  
  Roundtable discussion group  
  • Automatic Identification and Data Capture (AIDC) in  
    Healthcare: The world of GS1 Standards

• Wednesday, 14:00 – 15:30  (breakout session)  
  Roundtable discussion group  
  • Automatic Identification and Data Capture (AIDC) in  
    Healthcare: The world of GS1 Standards

• Wednesday, 14:00 – 15:30  (breakout session)  
  Roundtable discussion group  
  • Implementing Global Location Numbers (GLN) and the role of  
    the GLN registries
Global teams
• Implementation Guideline
• Location and Legal Entity ID
• Patient and Caregiver ID
• Multiple Barcodes
• Barcode / EPC Interoperability
• Phase 2: AIDC Application Standards

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

Peter Alvarez
GS1 Global Office
Topics

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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
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 CO</td>
</tr>
<tr>
<td>3M DIAGNOSTIC SYSTEMS INC</td>
<td>3M DENTAL 800-237-1659</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 MEDI SURGE</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 MEDICALSURG</td>
<td>3M OCC. HEALTH AND ENV. SAFETY DIV</td>
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<tr>
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<td>3M OCC. HEALTH AND ENV. SAFETY DIV</td>
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<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>3M FEDERAL GOVERNMENT</td>
<td>3M UNITEK</td>
</tr>
<tr>
<td>3M FEDERAL SYSTEMS DEPARTMENT</td>
<td>THREE M ESPE</td>
</tr>
<tr>
<td>3M HEALTH CARE SYSTEMS</td>
<td>3M COMPANY-OEM WAHL CORP.</td>
</tr>
<tr>
<td>3M HEALTHCARE $250 MINIMUM ORDER</td>
<td>3M COMPANY MINNESOTA SCIENTIF</td>
</tr>
<tr>
<td>3M HEALTHCARE-WINNIPEG MINING</td>
<td>3M CORPORATE ALLIANCE 3M CUSTOMER SERV</td>
</tr>
<tr>
<td>3M MEDICAL - CREDIT CARD</td>
<td>3M HEALTHCARE</td>
</tr>
<tr>
<td>3M MEDICAL PRODUCTS</td>
<td>3M MEDICAL - CREDIT CARD</td>
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<td>3M OCC. HEALTH AND ENV. SAFETY DIV</td>
<td>3-M COMPANY</td>
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<tr>
<td>3M OCCUPATIONAL AND SAFETY DIV</td>
<td>3-M COMPANY-OEM 0</td>
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<tr>
<td>3M SAFETY DIVISION</td>
<td>3-M COMPANY-OEM DENTAL 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>3-M HEALTHCARE</td>
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<td>3M DENTAL PRODUCTS DIV.</td>
<td>3-M DENTAL CARE</td>
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<td>3M UNITEK CORPORATION</td>
<td>3-M PUERTO RICO</td>
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<tr>
<td>3M UNITEK DENTAL PRODUCTS</td>
<td>3-M SPECIALITY CHEMICAL</td>
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<tr>
<td>3M BIOLOGICAL</td>
<td>3-M % SAN MAR</td>
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<tr>
<td>3M ESPE DENTAL PRODUCTS</td>
<td>3-M HEALT</td>
</tr>
<tr>
<td>3M HEALTHCARE (MEDISURG PRODS)</td>
<td>3-M MINNESOTA MI</td>
</tr>
<tr>
<td>3M O/E CHECKPOINT METO</td>
<td>3-M MINNESOTA MINING &amp; MFG,CO</td>
</tr>
</tbody>
</table>
## 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 unavailability 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%
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
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
Topics

- Background
- **Where we are going**
- Where we are today
- What this means to you
GDSN 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

GS1 GDSN
Global Data Synchronisation Network

Manufacturer

On boarding partner

Distributor/Wholesaler/GPO

Healthcare provider

© 2010 GS1
Results 2007 DoD Pilot

• **Opportunities identified to saves 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
In Australia our data synchronisation solution is the National Product Catalogue (NPC).

- Established by NEHTA in March 2006
- Healthcare branding of GS1 Australia’s GS1net
- Using GTINs as standard identifier, with standard data set and GDSN compliant
- For all healthcare items – medicines, devices and consumables
- Suppliers populate data once and publish to many

© 2010 GS1 Australia
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
Global GDSN Implementation Initiative for 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.
GDSN implementation attributes for Healthcare

- Global Trade Item Number (GTIN)
- Pack Level
- Manufacturer Part Number
- Hierarchy (Parent GTIN)
- Hierarchy (Child GTIN)
- Hierarchy (Quantity of Children)
- Publisher Global Location Number (GLN)
- Target Market
- Brand Owner and GLN
- Manufacturer Name and GLN
- Functional Name
- Brand Name
- Description
- Height + Unit of Measure
- Width + Unit of Measure
- Depth + Unit of Measure
- Gross Weight + Unit of Measure
- Net Content + Unit of Measure
- Consumer Unit Y/N
- Orderable Unit Y/N

- Invoice Unit Y/N
- Shipping Unit Y/N
- Base Unit Y/N
- Variable Unit Y/N
- Returnable Package Y/N
- Marked with Lot Number Y/N
- Bar code Type
- GPC code
- Optional Classification Agency
- Optional Classification Agency Value
- Start Date
- Effective Date
- Shelf Life From Production
- Shelf Life From Delivery
- 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
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

Gain access to the GDSN

Internal preparation and planning

Load products and register with Global Registry

Buyer subscribes to supplier and products

Continuous synchronisation of data

Synchronise more products with more trading partners

Streamline and optimise processes
GDSN session this week

This Week:

- Wednesday, 11:00 – 12:30  (breakout session)
  Roundtable discussion group
  - 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
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
Topics

• Background
• Where we are going
• Where we are today
• What this means to you
“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
Traceability Standards

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
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. Serial No. AI(21)), 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 Key** (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

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

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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

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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
Traceability across the supply chain
Topics

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

Global Traceability Standards for Healthcare

- 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
- GTSH & GTSCH IG V2

Ratified standard | Work finalised or near closure | Work in progress or planned

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Version 1.15 – November 2010
Global Traceability Standard for Healthcare

Business process and system requirements for supply chain traceability

Published 27 February 2009

Available at www.gs1.org
Implementation guide

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.
Traceability in Healthcare II (TH-II)

Global Traceability Standard for Healthcare (GTSH)
A Process Standard enabled by the GS1 System of Standards
And GTSH Implementation Guideline
Focus on EPCglobal and eCOM areas:

- Identified, prioritised and drafting **Core** Use Cases:
  1. Chain of Custody / Chain of Ownership
     1. EPCglobal JRG formed for Event-Based ePedigree
     2. BRs accepted
     3. Technical Gap Analysis underway
  2. Product Identifier Authentication
     1. BRAD in development
     2. Product Recall

DEVELOP / PUBLISH:
Global Traceability Standard for Healthcare (GTSH)
A Process Standard enabled by the GS1 System of Standards and
GTSH Implementation Guideline
Topics

• Background

• Where we are going

• Where we are today

• What this means to you
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…
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, 11:00 – 12:30  (breakout session)
  Roundtable discussion group
  • 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

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