Introduction to GS1 in Healthcare

Global GS1 Healthcare Conference
Buenos Aires, Argentina
Agenda

• GS1 Healthcare – the global perspective

• AIDC Application Standards Chuck.Biss@gs1.org

• Global Data Synchronisation & Product Classification Pete.Alvarez@gs1.org

• Traceability in Healthcare Janice.Kite@gs1.org

• Public Policy Geraldine.Lissalde.Bonnet@gs1.org
GS1: The Global Language of Business

- a neutral, not-for-profit, international organisation
- dedicated to the design and implementation of global standards
- to improve the efficiency and visibility of supply chains globally and across sectors
A need for global standards...

What happens when there aren’t global standards?

• Inefficiencies
• Increased risk
• Lost opportunities
... to meet the needs of the supply chains in different sectors

Efficiency  Safety  Collaboration  Sustainability

in Retail & Consumer Goods  in Healthcare  in Transport & Logistics  and more...
GS1 is both global and local

**GS1 Global Office**
Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

**GS1 Member Organisations**
Local offices in 111 countries around the globe
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...
Global reach, local presence

Close to 2 million companies around the world use GS1
Across 150 countries
Over 6 billion transactions a day
The healthcare supply chain needs global standards

- **Medication errors** result in additional treatments, disabilities and even loss of life
- **Counterfeiting** is an increasing global threat
- **Traceability** from manufacturer to patient is problematic
- **Product recalls** can be difficult to manage, in particular for healthcare providers
- **Manual interventions** in the healthcare supply chain decrease its efficiency and accuracy
Lack of standards in Healthcare is inefficient and adds risk…

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility
- No bar code – need to bar code; re-package; re-label
The Need for Global standards in Healthcare

Diverging country requirements
Manufacturing headache

“CUSTOMIZED ACTIONS MEAN COSTS!!
Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering – otherwise complexity and cost will continue to raise”

Senior Executive, MD company
GS1 Healthcare mission – a voluntary, global 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.
Leading healthcare organisations pave the way...

Buyer/Provider-side Organisations going global

Austria, Austria, France, France, Germany

Germany, Hong Kong, Ireland, Macedonia, Netherlands

Netherlands, Switzerland, USA, USA, USA
GS1 Healthcare around the World

Members global user group

Manufacturers
3M
Abbott Laboratories
AbbVie
Alcon Labs
Amgen
Astra Zeneca
Baxter
Becton Dickenson
B. Braun
Cook
Covidien
Edwards Lifescience
Fresenius
GE Healthcare
Genzyme
Gilead
GlaxoSmithKline
Johnson & Johnson
Medtronic
Merck & Co.
Pall Medical
Pfizer
Purdue Pharma
Smiths Medical
TEVA
Zimmer

Solution provider
Advanco
Axway
GHX
Seidenader
Excellis Health

Distributors/Healthcare providers/GPOs/T&L
Cardinal Health (U.S.)
CH Aulnay sous Bois (France)
Comparatio Health (Germany)
DHL Exel Supply Chain
Erasmus MC Rotterdam (NL)
Filip Vtori hospital (Macedonia)
UNI.HA (representing 17 French university hospitals)
Hong Kong Hospital Authorities
McKesson (U.S.)
Novation (U.S.)
Orthopädisches Spital Speising Wien (Austria)
Premier (U.S.)
St. James Hospital, Dublin
Marienhospital Herne (Germany)
UMC Groningen (NL)
University Kentucky Healthcare (U.S.)
Wiener Krankenanstaltenverbund (Austria)

Non-voting members
AHRMM
Cladimed
EDOM – Council of Europe
FDA USA
Instituto Brasileiro de Ética
Concorrencial – ETCO
Public Health Agency of Canada US DoD

Manufacturers
3M
Bayer
Becton Dickinson
Boehringer Ingelheim
Coloplast
Draeger Medical
Genzyme
Hospira
Kimberly-Clark
Novo Nordisk
Purdue Pharma
St. Jude Medical
Stryker
Teva Pharmaceuticals
Terumo
UCB
Upsher-Smith

Distributors/Wholesalers
Aexxdis
Amerinet
Amerisource Bergen
CH2
Depolabo
Galexis
GAMMA Wholesale
Geodis
McMahon
Owens & Minor

Healthcare providers/Retailers
Alfred Hospital (Australia)
Ascension Health (U.S.)
Capital District Health (Canada)
CHU de Québec (Canada)
CHU Dijon (France)
HUG Geneva (Switzerland)
London Drugs (U.K.)
Mayo Clinic (U.S.)
Sisters of Mercy (U.S.)
Sobeys Pharmacy (U.K.)
UHCS Augusta VA (U.S.)
Walgreens (U.S.)
Wal-Mart (U.S.)

Associations
AHA (U.S.)
CIP/ACL (France)
Chës (U.S.)
EFPIA (Europe)
Eucomed (Europe)
FENIN (Spain)
GIRP (Europe)
HDMA (U.S.)
International Hospital Federation
JFMDA (Japan)
Medical Industry Association of Australia
NACDS (U.S.)
Patient Safety Foundation (U.S.)

And many more…
Recognised, open and neutral source

And many more...
GS1 and Joint Initiative Council (JIC) in Healthcare

- International Organisation for Standardization
- European Committee for Standardization
- Health Level 7 international
- International Health Terminology SDO
- Clinical Data Interchange Standards Consortium
- Integrating the Healthcare Enterprise

Joint Initiative Council

- World Health Organization
- World Customs Organization
- International Society for Blood Transfusion
- European Association of Hospital Pharmacists
- European Association of Medical Device manufacturer
- International Society for Quality in Healthcare

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Agenda

• GS1 Healthcare – the global perspective

• AIDC Application Standards

• Global Data Synchronisation & Product Classification

• Traceability in Healthcare

• Public Policy
Topics

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

© 2013 GS1
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: 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

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• Questions
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” / “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

AIDC Application Standards for Healthcare

- GTIN Alloc Rules & AIDC Application Standards Phase 1 & Small Instrum. (finalised in 2009)
- Implementation guidelines (AIDC Ph 1, GLN, Plasma derivatives)
- Multiple bar codes
- Patient & Caregiver ID
- Level Below The Each/Unit Dose
- Updates & Clarifications

2011

2012

2013

Ratified standard or work finalised

Work 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

Available at: http://www.gs1.org/sites/default/files/docs/gsmp/healthcare/AIDC_Healthcare_Imp_Guide.pdf
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:

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<td>GTIN (Global Trade Item Number)</td>
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<td>GSRN (Global Service Relation Number) – Recipient</td>
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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**
- **Composite Component**
- **GS1-128**
- **DataMatrix**
- **ITF-14**
GS1 Data Carriers for Healthcare

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

GS1-128 & GS1 DataBar

GS1 DataMatrix
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...
How YOU can get started

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 related sessions...

This Week:

• Tuesday, 13:00 – 14:00
  “Implementation Reality”
  – GLN – GS1 Global Location Number, a basic key for traceability and other business processes
    Dennis Black, Director, e-Business, BD

• Wednesday, 14:00 – 15:00
  “Ask the Experts”
  – Ask the GS1 DataMatrix Expert
    Chuck Biss, Senior Director, AIDC Healthcare, GS1 Global Office
Join us!!!

Global teams

• GSMP Level Below The Each Mission Specific Work Group (MSWG)
• GSMP AIDC Healthcare Application Standard Updates Mission Specific Work Group (MSWG)

Local teams

• Contact your local Member Organisation representative
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Every company has a **database** filled with master data about the products they **make**, **sell**, or **buy**.

But when one company needs to **change** any bit of information in their database or **add a new item**, another database becomes outdated!
Managing master data

Where does the data come from?

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 a major GPO’s 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

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<td>3M HEALT</td>
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<td>3M - MINNESOTA MI</td>
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<tr>
<td>3M C/O CHECKPOINT METO</td>
<td>3M MINNESOTA MINING &amp; MFG CO</td>
<td>3M HEALT</td>
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**Multiple ways to list a manufacturer:**

**Who is who?**
Before Data Synchronisation

1. Product Info sent
   Errors in transposition

2. Product Info entered
   Errors in Translation
   Errors in Delivery / Transmission

3. Purchase Order

4. Query Order Errors

5. Adjusted Purchase Order

6. Despatch Advice

7. Goods Delivered

8. Query Delivery Errors / Claim for credit

9. Return Incorrect Goods

10. Adjusted Delivery

11. Delayed Settlement

Supplier / Broker

Buyer

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What is the cost of bad data?
Managing master data

Should we care?

Critical business processes require reliable product and location data:
- Distribution systems
- Inventory replenishment
- Clinical systems
- 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

How to improve?

Supplier = data source

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

Needs security
• Authorization 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
What is the solution?

The GS1 Global Data Synchronisation Network connects trading partners via a network of interoperable GDSN-certified data pools

Enables trading partners to share reliable master data
The Global Data Synchronization Network

1. Load GTIN Data
2. Register Data
3. Subscription Request
4. Publish Data

Source Data Pool
Recipient Data Pool
GS1 Global Registry™

Manufacturer
Distributor, wholesaler, GPO
Healthcare Provider / Retailer

GLN
GTIN
GLN
GTIN
GLN

Unit Case Pallet
Unit Case Pallet
Unit Case Pallet

© 2013 GS1
After Data Synchronisation

1. Populates
2. Publishes
3. Purchase Order
4. Query Order Errors
5. Adjusted Purchase Order
6. Despatch Advice
7. Goods Delivered
8. Query Delivery Errors / Claim for credit
9. Return Incorrect Goods
10. Adjusted Delivery
11. Delayed Settlement
For more information

www.gs1.org/gdsn
Contact Details

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T  +1 609 462 2625
Agenda

• GS1 Healthcare – the global perspective

• AIDC Application Standards

• Global Data Synchronisation & Product Classification

• Traceability in Healthcare

• Public Policy
Traceability in Healthcare

Janice Kite
Traceability Director Healthcare
Global Office
The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

- **Product**
  - Global Trade Item Number (GTIN)
  - Optional GTIN attributes such as lot number, serial number, expiration date
- **Location/Legal entity**
  - Global Location Number (GLN)
- **Logistic unit**
  - Serial Shipping Container Code (SSCC)
- **Asset**
  - Global Returnable Asset Identifier (GRAI)
  - Global Individual Asset Identifier (GIAI)
- **Document**
  - Global Document Type Identifier (GDTI)

CAPTURE
GS1 BarCodes and EPCglobal RFID

- **EAN/UPC**
- **ITF-14**
- **GS1 DataBar**
- **GS1 DataMatrix**
- **GS1-128**

SHARE

- **Master data**
  - Global Data Synchronisation Network (GDSN)
- **Transactional data**
  - Electronic business messaging
    - GS1 XML or EANCOM
- **Physical event data**
  - EPC Information Service (EPCIS)

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GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production\(^1\) to \(\text{Point of Use}^2\)

- All authentic \textbf{items} are identified with the appropriate \textbf{GS1 Identification Keys} (e.g. GTIN) and appropriate \textbf{Application Identifier} (AI, e.g. Serial No. AI(21)), if applicable, at point of production
- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life
- All \textbf{physical locations} are identified with the appropriate \textbf{GS1 Identification Key} (e.g. GLN) across the entire supply chain
- All \textbf{patients and care givers}, when in a care giving environment, are identified with the appropriate \textbf{GS1 identification Keys} (e.g. AI 8017; AI 8018)
- Agreed \textbf{master data} is captured and shared (e.g. via GDSN) amongst trading partners
- Agreed \textbf{transactional data} is captured and shared (e.g. via business-to-business messaging) amongst trading partners
- Agreed \textbf{event data} is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

\textbf{SO THAT:}

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
Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, 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
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights\(^3\) are achievable
- 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
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user
Traceability in Healthcare

Objective:
Ensure the GS1 System of Global Standards has both the process and technical standards necessary to achieve the GS1 Members Vision for Traceability in Healthcare

Approach: Two phases
TH-I - Process Standard - December 2007 to April 2009
TH-II – Technical Standards – April 2009 to date & ongoing
Traceability in Healthcare I (TH-I)

Delivered:

Global Traceability Standard for Healthcare (GTSH)
PUBLISHED 27th February 2009

GTSH Implementation Guideline
PUBLISHED 24th April 2009
Global Traceability Standard for Healthcare (GTSH) and Implementation Guideline (GTSH IG)
GTSH: A PROCESS STANDARD

• Definition of ‘Traceability’ - both track (downstream) & trace (upstream)
  “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”

  – Defines difference between ‘Internal’ and ‘External’ Traceability

• Establishes minimum model for Traceability: “One Up, One Down”

• Establishes key concepts:
  A. In parallel with the flow of product there has to be a flow of information about the product
  B. Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
  C. ‘Parties’ and ‘Roles’: Parties can have varying roles

• Details 18 Business Requirements (Needs)

• 30 Business Rules (Controls or Constraints)

• Details the corresponding GS1 [technical] standards used within information technology tools

GTSH is not:

• A law or regulation
• A replacement for safety or quality programs
• A replacement for a service or solution provider
GTSH “One up, One down”

Information Flow

Physical Flow

Traceability Partner

Traceability Partner

Traceability Partner

Traceability Partner
“The purpose of this document is to assist any/all stakeholders in the global healthcare supply chain to implement a traceability system in line with the GS1 Global Traceability Standard for Healthcare (GTSH) utilising the GS1 System of standards…

For products, in scope are all pharmaceutical products and all medical device products. Out of scope is implementation of traceability related to non-medical products supplied to Healthcare providers (e.g. food, information technology), blood and blood products.

For supply chain, the start and end points in scope are from manufacturer of finished goods, including products created in the care facility, throughout the product’s intended useful life. Out of scope is implementation of traceability related to patients and healthcare professionals (HCPs) and End of Life Environmental regulations (e.g. European Waste Electrical and Electronic Equipment (WEEE) Directive)”
Traceability Standards Development since 2007

CURRENT FOCUS
The GS1 System

Identify
GS1 Identification Keys & Attributes

✓

Track

Capture
GS1 BarCodes and EPCglobal RFID

✓

Traceability

Share

Master data
GS1 XML or EANCOM

Physical event data
EPC Information Service (EPCIS)

Transactional data
Electronic business messaging

✓

GSN

80
TH-II: Physical Event Data

IDENTIFY
GS1 Identification Keys & Attributes

Track
- Trace
- Authentication
- Pedigree
- Returns
- Recalls

CAPTURE
GS1 BarCodes and EPCglobal RFID

SHARE
- Master data
  - Global Data Synchronisation Network (EAN/SN)
- Transactional data
  - Electronic business messaging
    - GS1 XML or EANCOM
- Physical event data
  - EPC Information Service (EPCIS)

Product
- Global Trade Item Number (GTIN)
- Optional GTIN attributes such as lot number, serial number, expiration date

Location/Legal entity
- Global Location Number (GLN)

Logistic unit
- Serial Shipping Container Code (SSCC)

Asset
- Global Returnable Asset Identifier (GRAI)
- Global Individual Asset Identifier (GIAI)

Document
- Global Document Type Identifier (GDTI)
Physical Event Data > Visibility Recall example

- **What:** what physical objects were involved (e.g. sGTIN in a GS1 Carrier)
  e.g. (01)10222222333334(21)12344(10)A1345B

- **When:** when the event took place (timestamp)
  e.g. 110922 (22nd September 2011)

- **Where:** where the event took place (e.g. GLN)
  e.g. 750620605 (Goods In, The General Hospital)

- **Why:** what business process step was being carried out (e.g. receiving, shipping…)
  Receiving

The 4 W’s
TH-II Project Strategy

✓ Phase I: *March 2009 – September 2011*
  ✓ Create list of Use Cases
    • Chain of Custody / Chain of Ownership (CoC/CoO)
    • Product Identifier Authentication
  ✓ Gather Business Requirements for each Use Case
  ✓ Determine work of Phase II (and subsequent phases)

✓ Phase II: *January 2012 – March 2012*
  ✓ Standards Gap Analysis to identify
    • Technical Models: Centralised, Semi-Centralised, Distributed
    • where a new standard(s) might be necessary
    • where existing standard(s) might need changing
  ✓ Develop necessary Work Request(s) (WRs)
TH-II Project Strategy

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    • where existing standard(s) might need changing
  ✓ Develop necessary Work Request(s) (WRs)
### Background Information - Standards Gaps vs Models

<table>
<thead>
<tr>
<th>Standards Gap</th>
<th>Centralized Models</th>
<th>Distributed Models</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Definition of EPCIS events needed to form pedigree</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>2 CBV enhancements to support above</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>3 Definition of pedigree checks, given events are gathered</td>
<td>✔</td>
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<tr>
<td>4 Central checking service request/response protocol</td>
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<td>✔</td>
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<td>5 Choreography/security for centralized models (including use of ONS for semi-centralized)</td>
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<td>✔</td>
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<tr>
<td>4 &amp; 5 includes addressing gaps for Product Identifier Authentication (PIA)</td>
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<td>✔</td>
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<td>Choreography/security for distributed models (including use of Discovery Services in some models)</td>
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<td>“Router” service</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

= First Priority

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Traceability in Healthcare MSWG:
Pedigree Security, Choreography and Checking Service (SCCS) MSWG

• Goal
  Develop standards to allow pharmaceutical supply chain parties striving to meet pedigree regulation requirements, focused on gathering and checking pedigree event data. Standards will also address data confidentiality and integrity. This MSWG will create A) standard for security framework applicable to EPCIS and Discovery Services and B) pedigree checking service.

• Status
  MSWG established and meeting regularly

• Timeline
  BRAD eBallot June 2013
Traceability in Healthcare MSWGs:
Enable Network Pedigree MSWG

• **Goal**
  Create new standard to enable Pedigree validation – a ‘profile’ standard above EPCIS that defines the types of EPCIS events and fields… that need to be captured for pedigree data. Will also define which tests need to be performed to verify pedigree data validity and integrity.

• **Status**
  MSWG currently on hold due to US pilots in progress; gap analysis

• **Timeline**
  Scheduled to start Q2 2013
Where are we now

• **WR12-126**  
  – Approval of Statement of Business Need to enable Mission Specific Work Group (MSWG) to form and begin work – by June 2013  
  – Completion estimated end Jun 2015

  – Developing BRAD – scheduled completion end of June 2013  
  – Completion estimated end June 2014

• **WR11-213** [http://community.gs1.org/apps/org/workgroup/gsmpepcis1_1cbvmswg/](http://community.gs1.org/apps/org/workgroup/gsmpepcis1_1cbvmswg/)  
  – BRAD completed to progressed to community review  
  – Completion estimated end December 2013
Traceability Framework

Chain of Custody
Chain of Ownership

Discovery Services

Product Identifier Authentication

Pedigree Security
Choreography, Checking
Service WR 12-127

EPCIS &
Core Business
Vocabulary 1.1
WR 11-213

Enable Network
Pedigree
WR 12-126

ON HOLD

Gaps in Scope WR12-127

GS1 US Healthcare Implementation
Guideline

GAP Analysis

US Healthcare-Specific

NEW Gaps (WR(s))
(i.e. not US Local,
WR12-126, WR12-127)

Traceability Event
Sharing Standards
Maintenance Group
(SMG)

Local

Event-Based
Chain of Custody /
Chain of Ownership & Product
Identifier Authentication

Active working group

Requirements from earlier groups

Future working group

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The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

- Product: Global Trade Item Number (GTIN)
- Location/Legal entity: Global Location Number (GLN)
- Logistic unit: Serial Shipping Container Code (SSCC)
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- Document: Global Document Type Identifier (GDTI)

Optional GTIN attributes such as lot number, serial number, expiration date

CAPTURE
GS1 BarCodes and EPCglobal RFID

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- ITF-14
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SHARE

- Master data: Global Data Synchronisation Network (GDSN)
- Transactional data: Electronic business messaging
  GS1 XML or EANCOM
- Physical event data: EPC Information Service (EPCIS)
Contact Details

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W www.gs1.org/healthcare
Agenda

• AIDC Application Standards
• Global Data Synchronisation & Product Classification
• Traceability in Healthcare
• Public Policy
GS1 Healthcare Public Policy

Introduction to Healthcare Public Policy Work Team

23rd Global Conference Buenos Aires
Public Policy WT Charter - *Purpose*

- Provide **strategic leadership in the conduct and interaction** with global public policy makers promoting harmonization of product identification at global level
- Provide a **forum for open exchange of information** between members
- **Monitor the global regulatory landscape** around the topics of healthcare and determine priorities for GS1 to engage in and act upon
- Establish a framework and **repository of global regulations** related to Healthcare: GS1 Healthcare Public Policy DataBase
Meetings are scheduled **bi-weekly** and held via **teleconference**

- Meeting notices are sent to membership via Microsoft Outlook
- Currently scheduled on Wednesdays

  - CET 16:30 – 17:30
  - EST 10:30 – 11:30
  - GMT 15:30 – 16:30

**All documents available online in GS1 HCPP Community room**

Registration necessary – access only for GS1 Healthcare members
Public Policy WT Charter - Purpose

• Provide strategic leadership in the conduct and interaction with global public policy makers promoting harmonization of product identification at global level
• Provide a forum for open exchange of information between members
• Monitor the global regulatory landscape around the topics of healthcare and determine priorities for GS1 to engage in and act upon
• Establish a framework and repository of global regulations related to Healthcare : GS1 Healthcare Public Policy DataBase
Country development adoption slides

• Developed by GS1 Healthcare Public Policy Work Team

• Complete and updated overview of regulatory dev. worldwide

• Access to this slide-deck is limited to members of GS1 Healthcare

• GS1 legal dept. included a *copy-right notice*: should not be used without GS1 authorisation and should not be circulated outside of GS1 Members.
Public Policy WT Charter - Purpose

- Provide **strategic leadership in the conduct and interaction** with global public policy makers promoting harmonization of product identification at global level
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- Monitor the global regulatory landscape around the topics of healthcare and determine priorities for GS1 to engage in and act upon
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GS1 HC Public Policy Database

• Online repository: [http://healthcare.gs1.org/pp/](http://healthcare.gs1.org/pp/)

• Relevant latest regulatory requirements at national, regional and local levels

• Information received by:
  – worldwide network of over 111 GS1 MOs,
  – members of the global GS1 Healthcare community,
  – Healthcare governmental bodies and regulators

• **Access to this DataBase is limited to members of GS1 Healthcare**
Welcome!
This database provides the latest relevant regulatory requirements, stakeholder agreements and user requests related to Healthcare product identification, product catalogues and traceability at national, regional and local levels.

Login

Not yet a member?
This information is only accessible for global GS1 Healthcare members and GS1 Member Organisations. Each registration application will require approval by GS1.

- [Register here](#) to access the GS1 Healthcare Public Policy Database
- [Join GS1 Healthcare](#)
GS1 Healthcare Public Policy Database - Browse database

This browser shows the regions and countries which are in the database. You can sort them alphabetically following the different sections of the table by clicking on the section title.

For a quick search you can also enter date (dd-mmm-yyyy) or text format

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Public Policy WT Charter - Communication

– Serve as representatives of GS1 Healthcare, in interactions with local MOs, for communication and consultation with global public policy makers

– Provide a communication plan and structured templates as a means to providing a consistent approved communications
Outreach/Communication:

Responses, Position Statements, Fact Sheets

• Submission to TGA public consultations

• Letter to Saudi Arabia FDA providing comments on the draft Guidelines on barcoding

• Comments on US FDA UDI proposed rule and on EU draft Recommendation on UDI

• Draft Discussion paper on Mobile Authentication Services for pharmaceuticals
Join our Public Policy Working Lunch on Wednesday from 13.00 to 15.00
Contact Details

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• Géraldine Lissalde-Bonnet
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