

The World of GS1 Standards: An Introduction

GS1 Healthcare Primer Session Washington DC, 16 June 2009





GS1 Standards in Healthcare

Improve patient safety & Increase efficiency and save costs





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Global, open supply chain standards

- Automatic Identification & Data Capture (AIDC)
 - Bar codes
 - Radio Frequency Identification (RFID)
- Traceability
- Master data alignment
- Electronic Data Interchange (EDI)



Standards What's in it for me?



Speak one language.

Standards are agreements that structure any activity or any industry – rules that everyone applies.

- ✓ Open
- Neutral
- ✓ Simple
- Technology-independent



Global Standards *What's in it for me?*



The healthcare supply chain today is global.

Global standards reduce complexity for multi-national suppliers.

- Production & Packaging
- Supply chain management

More cost effective for everyone.

Lack of Global Standards So what?

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Sogini Peder

Singial Redea

Which barcode to scan?

Soghi Pedec

Sim/ini

Diverging country requirements

6 different bar codes on 1 package

Sagial | Pedeo

GS¹ Healthcare

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FUNDLESSAND

Pedea

5 mg/ml

5 mg/ml



Lack of Global Standards So what? (2)

Diverging country requirements Manufacturing headache Country A 12345678912345(17)101230(10)A234VC2 Country B Country Country D. South A (01)30012345678906(17)101230(10)C4324(21)23

Additional cost and risk

Healthcare Lack of Global Standards So what? (3)



Additional cost and risk

Diverging country requirements No barcode available or an unusable one Requires (re-)barcoding by the hospital (or a 3rd party provider)



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Supply chain standards *What's in it for me?*



Distributor, wholesaler, GPO, ...

The healthcare supply chain ... Healthcare (GS1 in real life





Multi-sectoral standards What's in it for me?



Medical equipment

Food & beverages, office supplies, personal care, tools, etc.



- Global standards to improve the efficiency and visibility of supply chains globally and across sectors
- Not-for-profit organisation
- Global organisation





108 Member Organisations - 150 Countries served

GS1 Healthcare GS1 System of Standards



GS1 Healthcare GS1 System of Standards



Global

- Integrity of the system worldwide (unique numbering across borders)
- Worldwide network of GS1 Member Organisations (108 in total) to support adoption and implementation

Open

- No barriers
- Ensures full interoperability

Proven

- In use for 30+ years in Retail
- The most widely used system of standards in the world across 20+ sectors

USI Healthcare 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**.



AIDC Application Standards

Data Synchronisation & Product Classification

Traceability in Healthcare





Basic Principles of GS1 Automatic Identification and Data Capture (AIDC)

Chuck Biss, GS1 Global Office





Define which data to carry on which data carrier for any Healthcare product at all packaging levels

Healthcare The Foundation of the GS1 System IGS1

GS1 Identification Keys

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



GS1 Healthcare GS1 Identification Keys

Item identifier = **GTIN**

Global Trade Item Number

Logistics unit identifier = **SSCC**

Serial Shipping Container Code

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

Location identifier = **GLN**

Global Location Number

And more ...

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GS1 Healthcare GS1 Identification Keys

GTIN = Global Trade Item Number Products or Services SSCC= Serial Shipping Container Codes Individual Logistics Units

GLN = Global Location Numbers Legal or Functional Entities and Locations

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

Healthcare Allocation of GTIN's



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Brand owners allocate GTIN's based on standardised allocation rules, for example:

- 1 GTIN = 1 product
- 1 product = 1 GTIN
- Different GTIN for each packaging level
- Change GTIN when pack of 20 becomes pack of 25
- Add language, same GTIN
- Change language, new GTIN
- Never re-allocate a GTIN to another product !

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GTIN Allocation Rules for Healthcare



- Voluntary guideline developed by GS1 Healthcare providing simple examples tailored for the global Healthcare sector
- Consistent with the general GTIN Allocation Rules
- Products in scope:
 - Pharmaceuticals (OTC and Rx)
 - Medical devices
- Local regulations may apply and take precedence over this voluntary guideline

Available online at www.gs1.org/healthcare



GS1 General Specifications:

Complete list of 100+ GS1 Application Identifiers

Including:

- Expiry date
- Lot number
- Serial number
- Logistics measure





GS1 Data Carriers include bar codes and RFID

Scanner / Reader



Data carrier

GS1 Healthcare Data Carriers: Features

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 Healthcare GS1 Data Carriers: Basic Bar Code System



Host Scanner / Reader Bar Code Module Label / Mark





EAN/UPC







Composite Component



(01) 00012345678905 GS1

DataMatrix



ITF-14

GS1 Healthcare GS1 Data Carriers: Basic RFID System





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Image: Market Market

Four main 'globally established' frequencies on which RFID operates

- Low Frequency (LF): 125 132 kHz
- High Frequency (HF): 13.56 MHz
- Ultra High Frequency (UHF): 850 950 MHz
- Microwave .2.4 GHz

GS1 Healthcare Healthcare specific requirements





Expiration data & lot number

Small space



Direct part marking



Additional data & variable data at high production rates



Non-retail channels
And more...

GS1 Healthcare Supplying products & exchanging information







Define which data to carry on which data carrier for any Healthcare product at all packaging levels



Basic Principles of Data Synchronisation

Peter Alvarez, GS1 Global Office





Develop a data synchronisation standard to enable Healthcare stakeholders to leverage GDSN for reliable data





Managing Master Data Should we care?

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

Healthcare Managing master data How does it work 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)

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No standardised product identification

Same product – different numbers

For example*:

3M product with reference # 8630 Same product in different databases of distributors:

 Allegiance 	M8630
•Owens & Minor	4509008630
•BBMC-Colonial	045098630
•BBMC-Durr	081048
•Kreisers	MINN8630
•Midwest	TM-8630
•Pacific	3/M8630
 UnitedUMS 	001880

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"



No standardised location identification

Manufacturer	Manufacturer	
SOUTHLAND TECHNOLOGY 3M	3M 800-327-5380	3M C/O EE
3M CO PHOTO PRODUCTS DIV	3M CO	3M C/O FL
3M DIAGNOSTIC SYSTEMS INC	3M DENTAL 800-237-1650	3M C/O G(
3M ELECTRICAL SPECIALTIES DIV	3M ESPE DENTAL DIVISION 800-364-3577	3M C/O H
3M HEALTH	3M ESPE UNITED STATES	3M C/O IN
3M HEALTH CARE CDI	3M ESPE	3M C/O JA
3M HEARING COMPONENTS	3M HEALTH CARE 800-521-2818	3M C/O LU
3M INDUSTRIAL TAPES LTD	3M HEALTHCARE PRODUCT	3M C/O N/
3M MEDICAL DEVICE DIV	3M HEALTHCATE	3M C/O NC
3M MEDICAL IMAGING SYSTEMS DIV	3M MEDSURGE	3M C/O O\
3M MEDICAL PRODUCTS DIV	3M MINNESOTA MINING MFG OFFICE	3M C/O RE
3M MEDICAL-SURGICAL DIV	3M MINNESOTA MINNING & MFG.CO.	3M C/O SA
3M MEDICAL/SURG	3M OCC. HEALTH AND ENV. SAFETY DIV	3MIC/OIS(
3M PHARMACEUTICS AND MEDICAL S	3M OCC. HEALTH AND ENV. SAFETY DIV.	3M C/O TH
3M-MEDICAL/SURGICAL	3M SARNS/CDI	3M C/O TH
3M/ OCCUPATIONAL AND SAFETY DIV	3M SURGICAL	3M C/O TH
3M - MINNESOTA MINING &	3M UNITEK 800-423-4588	3M C/O TIN
CO	3M UNITEK	3M C/O W
3M FEDERAL GOVERNMENT	THREE M/ ESPE	3M C/O W
3M FEDERAL SYSTEMS DEPARTMENT	3M COMPANY C/O WAHL CORP.	3M COMM
3M HEALTH CARE SYSTEMS	MINNESOTA SCIENTIF	3M COMM
3M HEALTHCARE \$250 MINIMUM ORDER	CORPORATE ALLIANCE 3M CUSTOMER SERV	3M COMP.
3M HEALTHCARE(MINNISOTA MINNING)	3 M HEALTHCARE	3M COMP.
3M MEDICAL - CREDIT CARD	3 M UNITEK CORP	3M COMP.
3M MEDICAL PRODUCTS	3-M	3M COMP.
3M OCC. HEALTH AND ENV. SAFETY DIVISION	3-M COMPANY	3M COMP.
3M OCCUPATIONAL AND SAFETY DIV	3-M COMPANY-C/O O	3M COMP.
3M SAFETY DIVISION	3-M COMPANY-C/O OEM PRODUCTS	3M CONS
3M-DENTAL PRODUCTS DIVISION	3-M PHARMACEUTICALS	3M CONS
3M-HEALTH CARE	33M HEALTHCARE	3M CORP
3M DENTAL PRODUCTS DIV.	3M	3M DENT/
3M UNITEK CORPORATION	3M PUERTO RICO	3M DENT/
3M UNITEK DENTAL PRODUCTS	3M SPECIALITY CHEMICAL	3M DEUTS
3M BIOLOGICAL	3M % SAN-MAR	3M HEALT
3M ESPE DENTAL PRODUCTS	3M (CRJ7242)	3M HEALT
3M HEALTH CARE (MED/SURG PRODS)	3M - MINNESOTA MI	3M HEALT
3M C/O CHECKPOINT METO	3M - MINNESOTA MINING & MFG.CO	3M HEALT

Multiple manufacturer names

Order from whom?



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

•Autorisation access by supply chain partners

Standards-based

Standard identification keys
Predefined (set of) product attributes

Hospital = data recipient Needs single point-oftruth

- •One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

- Standard identification keys
- •Consistently formatted information
- Complete information

HealthcareManaging Master Data
How to improve? (2)



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GS1 Healthcare Global Data Synchronisation

Global Data Synchronisation Network (GDSN)



Governance by a neutral, not-for-profit body:



Healthcare How GDSN works

1. Load data

Source internal

Source

datapool

GS1

Recipient

datapool

Recipient

database

internal

Global

Registry

database

• 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

4



Develop a data synchronisation standard to enable Healthcare stakeholders to leverage GDSN for reliable data



GS1 Traceability in Healthcare Work Team

Janice Kite, GS1 Global Office





Develop a suite of standards to **enable traceability** of healthcare products from point of production to point of use





Traceability is the ability...

to track forward the movement through specified stage(s) of the extended supply chain and...

to trace backward the history, application or location of that which is under consideration



GS1 Healthcare Traceability matters because of...

- ... regulatory compliance
- ... anti-counterfeiting/diversion
- ... product recalls
- ... adverse event reporting and postmarket surveillance
- ... medical error reduction
- ... documenting medical product use in Electronic Health Records (EHR) and Hospital Information Systems (HIS)
- ... efficient logistics management

GS1 Healthcare GS1 Vision Traceability in Healthcare



Full actionable visibility of all items in healthcare is possible from point of production to point of use across geographies globally

Healthcare Enabling Traceability in the Healthcare Supply Chain



A suite of GS1 Standards enabling traceability throughout the Healthcare supply chain

GS1 Process Standards

(GTSH)

GS1 AIDC Application Standards

(GS1 ID keys & data carriers)

GS1 Technical Standards

(EPCIS, GDSN, ONS, Discovery)

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GS1 Healthcare How Does Traceability Work?

The GS1 Global Traceability Standards provide guidance on how to implement effective traceability solutions

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



GS1 Healthcare 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





Cumulative Tracking (e.g., California ePedigree)

Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.





Single Source Database

The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a Third Party.



GS1 Healthcare Information Sharing Model 4

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.



GS1 Healthcare Available for download at www.gs1.org/healthcare

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GS1 Standards Document

Business Process and System Requirements for Supply Chain Traceability

Global Traceability Standard for Healthcare

Issue 1.0.0, Feb-2009

GS1 Global Traceability Standard for Healthcare (GTSH) Implementation Guide

Issue 1, April-2009







Develop a suite of standards to **enable traceability** of healthcare products from point of production to point of use



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