

The world of GS1 standards in healthcare

Singapore, 9 November 2010



Healthcare Agenda

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



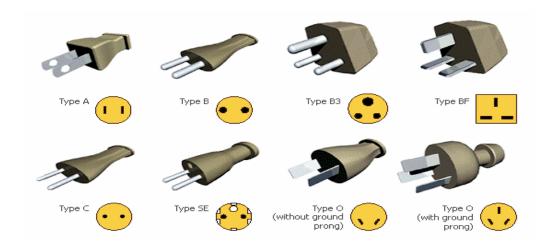
- Background
- Where we are going
- Where we are today
- What this means to you



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Healthcare Lack of global standards...







Healthcare 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.

(GS1 Healthcare Global standards in Healthcare?





Healthcare Global standards in Healthcare?





Healthcare Global standards in Healthcare?



(Re-)Labeling and repackaging by Healthcare providers...



Security, traceability and efficiency in healthcare

are currently at the forefront of government regulations and industry concerns around the world.



- 1. Improving patient safety
- 2. Increasing supply chain efficiency
- 3. Ensuring regulatory compliance





The healthcare supply chain...

simplified



Distributor, wholesaler, GPO, ...



The healthcare supply chain ...

in real life



Dis





Internet



Consumer

acture!

Transporter providers









Counterfeiter



Healthcare provider





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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.



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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Healthcare 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

Healthcare GS1 around the world



GS1 Member Organisation

Countries served on a direct basis from GS1 Global Office (Brussels) 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.



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





Hong Kong

Switzerland











Austria

Germany

USA

Austria

USA













Ireland

Netherlands

France

USA

USA



Healthcare 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



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Healthcare How to get started

- for
- 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 & Data Capture (AIDC)

"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)."





Defines
the data to carry
using specific data carriers
for every healthcare product
at every packaging level



Data – a few examples:

- ✓ Global Trade Item Number (GTIN)
 –
- ✓ Expiry Date
- ✓ Batch / Lot
- ✓ Serial Number







GS1-128 & GS1 DataBar



GS1 DataMatrix



EPC/RFID



Healthcare Scope: All healthcare products

Pharma / Vaccine / Nutritional



Medical devices



Retail

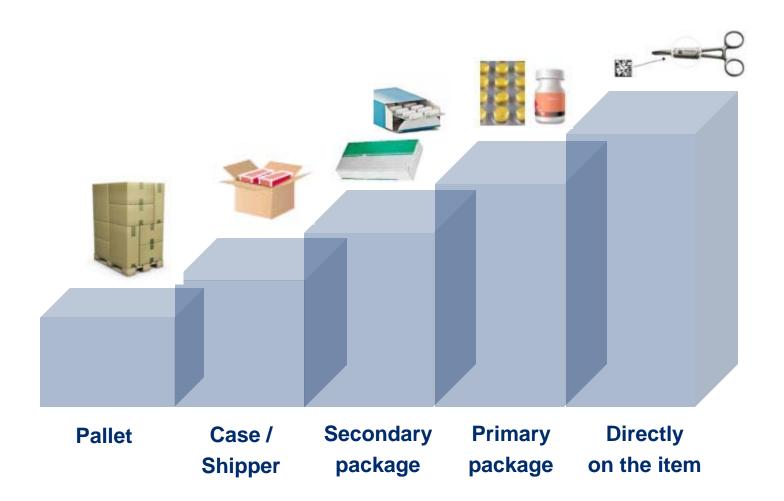


Non-retail





Healthcare Scope: All packaging levels





Scope: Solutions based on information needs



Cotton balls, bandages, patient exam gloves, ...



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ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step...





Healthcare 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



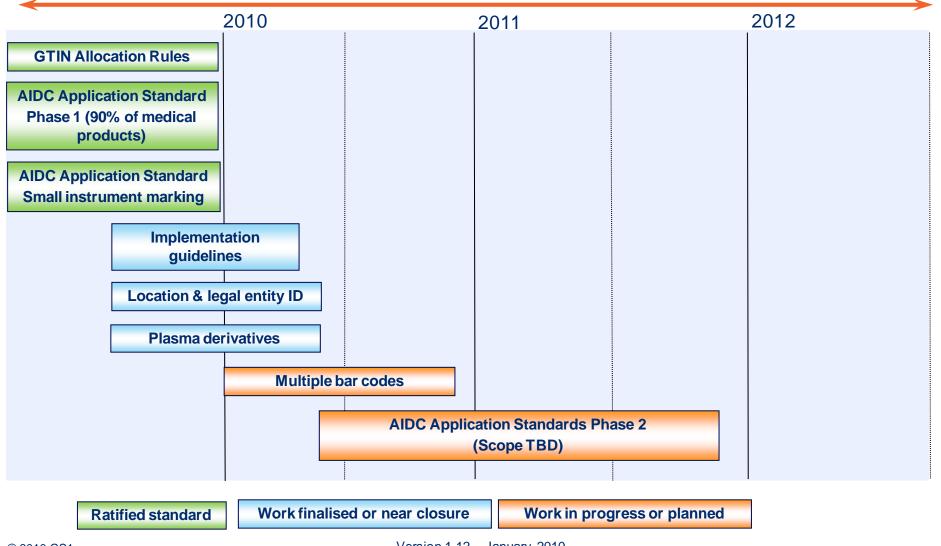


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Healthcare Roadmap to global standards

AIDC Application Standards for Healthcare





Healthcare GS1 General Specifications

Revised!



The core standards document of the GS1 System

Now including AIDC Application Standards for Healthcare

GS1 General Specifications Version 10

Issue 1, Jan-2010

And specific standards for marking re-usable surgical instruments



Contact your GS1 Member Organisation for your copy!



Healthcare AIDC Implementation Guide

In final draft!



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

Coming soon!!

AIDC Healthcare Implementation Guide

ksue 1, Draft 10, 28-Jan-2010





AIDC Application Standards for Healthcare and Product Marking Grid

$((GS)_1)$	AIDC Application Standards for Healthcare and Product Marking Grid							
	MINIMUM Level of AIDC Marking (Retail)		MINIMUM Level of AIDC Marking (Non-Retail)		ENHANCED Level of AIDC Marking		HIGHEST Level of AIDC Marking	
	Pharmaceuticals	Medical Devices	Pharmaceuticals	Medical Devices	Medical Devices	Medical Devices	Pharmaceuticals	Medical Devices
			Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Primarily Via Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Via Retail and/or Non-Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels
Description of the Example Product Hierarchy	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills	DPM: 1 consumer bandage Primary Package: 1 bandage in pouch	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills	DPM: 1 empty syringe Primary Package: 1 empty syringe in blisterpack	DPM: 1 contact lens Primary Package: 1 contact lens in vial	DPM: 1 catheter (temporary) Primary Package: 1 catheter in blisterpack	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills	DPM: 1 re-usable scalpel handle Primary Package: 1 re-usable scalpel handle in pouch
	Secondary Package: 3 blisterpacks of 36 pills in one carton	Secondary Package: 12 pouched bandages in one carton Case: 12 cartons (144 bandages)	3 blisterpacks of 36 pills in one carton	Secondary Package: 12 empty blisterpacked syringes In one carton	Secondary Package: 2 vials of 1 contact lens each in one carton	Secondary Package: 6 blisterpacked catheters in one carton	Secondary Package: 3 blisterpacks of 36 pills in one carton	Secondary Package: 6 pouched re-usable scalpel handles in one carton
	Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	Pallet: 200 cases (28,800 bandages)		Case: 12 cartons (144 syringes) Pallet: 200 cases (28,800 syringes)	Case: 12 cartons (24 contact lenses) Pallet: 100 cases (2,400 lenses)	Case: 24 cartons (144 catheters) Pallet: 200 cases (28,800 catheters)		Case: 15 cartons (90 scalpel handles) Pallet: 200 cases (18,000 handles)
Direct Part Mark (AIDC marked directly onto a single, unpackaged, unla- beled item)	No marking		No marking	No marking	No marking	No marking	No marking	GTIN Serial No Not for Implants Hospital: - 8003/8004 - optional
Primary Package (AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of 1 single item, or a group of items for a single therapy such as a Kit.)	No marking (mark with GTIN if no Secondary Package)	No marking (mark with GTIN if no Secondary Package)	GTIN	No marking (mark with GTIN if no Secondary Package)	No marking (mark with GTIN if no Secondary Package)	GTIN Lot Expiry	GTIN Hospital: Al(01)+Al(21)+Al(7003)	GTIN Lot Expiry Sertal No. Potency (kits) Hospital: - 8003/8004 - optional
Secondary Packaging (AIDC marked onto the next level of packaging, containing one or more single items in their Primary Packaging)	GTIN	GTIN		GTIN Lot Expiry	GTIN	GTIN Lot Expiry	Need 2 marks GTIN Hospital: Lot Al(01)+Al(21) Expiry + Al(7003) Sertal No. Potency	GTIN Lot Expiry Sertal No. Potency (kits) Hospital: - 8003/8004 - optional
Case / Shipper (AIDC marked onto a shipping container. May contain one or more items In their Primary Packaging and/or Secondary Packaging.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: -GTIN -Lot -Expiry Logistics: -SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN Logistics: - Lot - SSCC - Expiry Hospital: - Serial No. Al(01)+Al(21) - Potency +Al(7003)	Trade Item: - GTIN - Lot - Expiry - Serial No Potency Logistics: - SSCC
Pallet (AIDC marked onto a pallet. May contain one or more Case / Shippers.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SCC	Trade Item: -GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSC	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSCC



GS1 Identification Keys

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





ono 20

GS1 Healthcare GS1 Identification Keys



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 ...



Healthcare 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



Key attributes

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

Application Identifiers for healthcare use:

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
17	Expiry Date
21	Serial Number
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)



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





Healthcare GS1 BarCodes for Healthcare





GS1 DataBar





GS1-128



(02) 5 0123456 78901 7 (37) 000288 (02) 5 0123456 11111 5 (37) 000045



GS1 DataMatrix

(01)00012345678905



00012345678905

ITF-14

© 2010 GS1 51



Healthcare GS1 Data Carriers for Healthcare



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







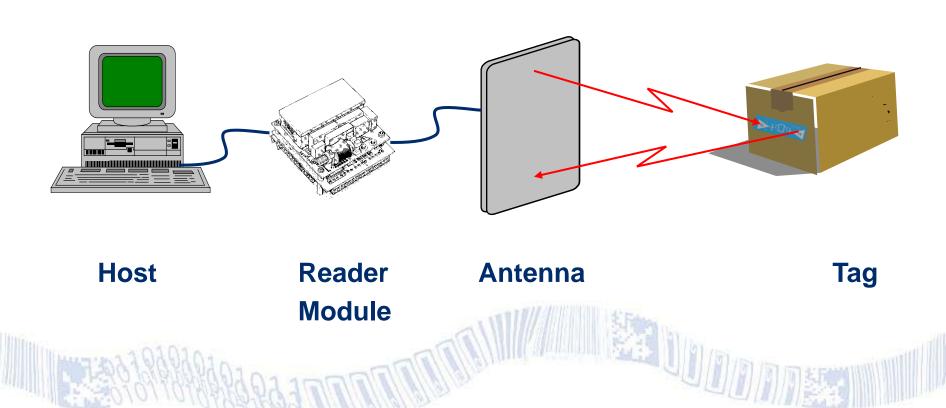
GS1-128 & GS1 DataBar



GS1 DataMatrix



Basic RFID system





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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...

Healthcare 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"...

(GS₁

Healthcare 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





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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)



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 product information

Inconsistent packaging data

- Order 20 cases, receive 20 boxes
- No uniform Unit of Measure standard

Unit of Measure	Description	Unit of Measure	Description
BD	BOARD FOOT	LOT	LOT
BDFT BN	BOARD FOOT BUNDLE	LOTS LY	LOT (MULTI) LINEAR YARD
BO	BOLT	LYRS	LINEAR YARD
BOLT	BOLT	NU	NUT
BR	BARREL	NUTS	NUT
BRRL	BARREL	OZ	OUNCE
BX	BOXES	ozs	OUNCES
BXES	BOXES	PA BADS	PAD PAD
COIL	COIL	PADS PI	PINT
CR	CARBOY	PINT	PINT
CRBY	CARBOY	PK	PACKAGE
cs	CASE	PKGS	PACKAGE
CSES	CASE	PL	PAIL
CT CTON	CARTON CARTON	PLS PR	PAILS PAIR
DR	DRUM	PRS	PAIR
DRUM	DRUM	QR	QUIRE
DZ	DOZEN	QRES	QUIRE
DZEN	DOZEN	QT	QUART
EA	EACH	QTS	QUART
EACH FE	EACH FEET	RE REAM	REAM REAM
1 -	I LL I	IXLAW	INCAM



Healthcare No standardised location ID

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 NA
3M MEDICAL DEVICE DIV	3M HEALTHCATE	3M C/O NO
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	3M C/O SC
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 TIV
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 CONSI
3M-HEALTH CARE	33M HEALTHCARE	3M CORP
3M DENTAL PRODUCTS DIV.	3M	3M DENTA
3M UNITEK CORPORATION	3M PUERTO RICO	3M DENTA
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 with whom?

Healthcare Data errors in healthcare

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

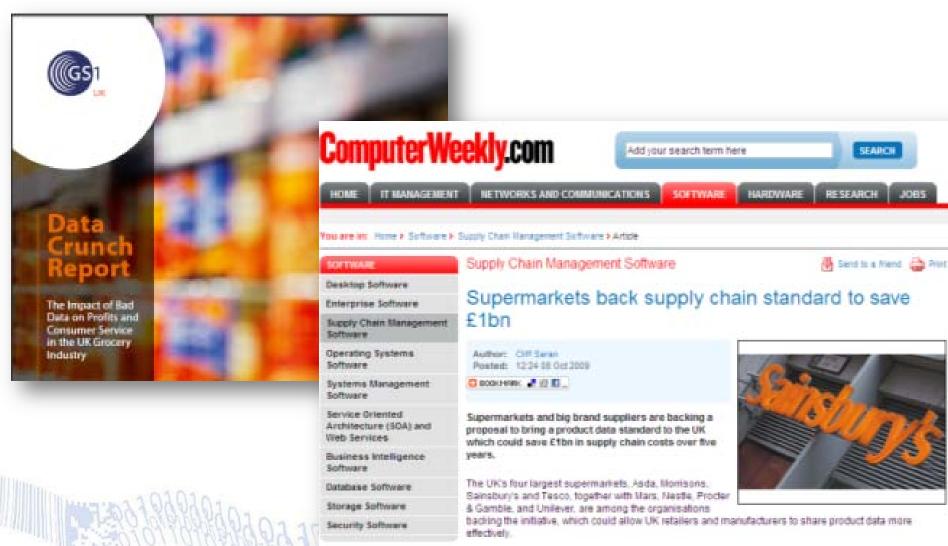
Source: US Department of Defense Study

Healthcare 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...





Healthcare A few examples





Supplier = data source Needs single point-ofentry

 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

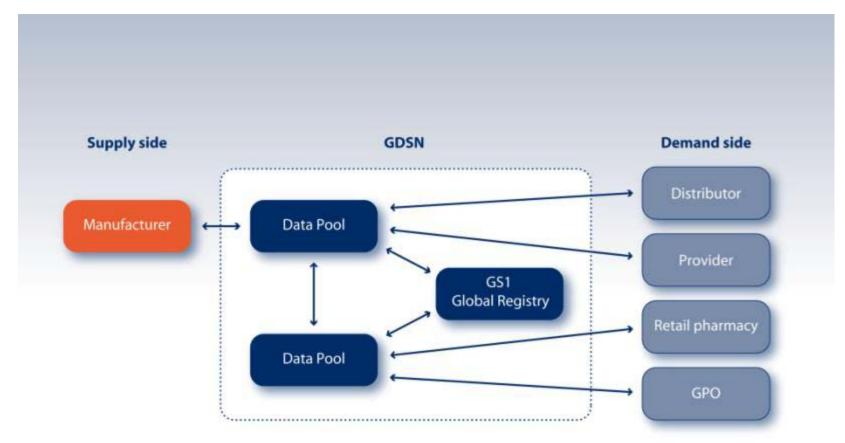
- One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

- Standard identification keys
- Consistently formatted information
- Complete information

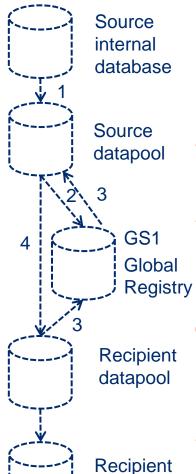


Healthcare Global Data Synchronisation





Healthcare How GDSN works



internal

database

1. Load data

The seller registers product and company information in its data pool

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



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



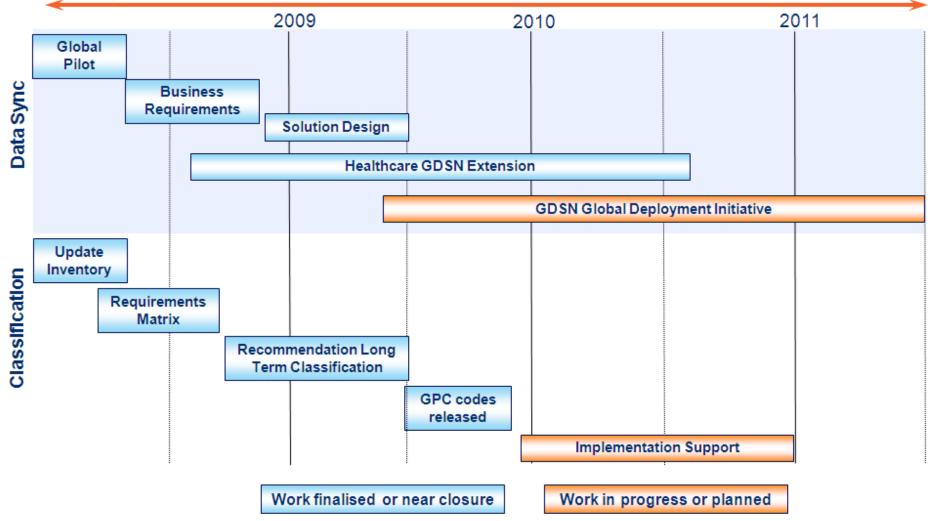


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Healthcare Roadmap to global standards

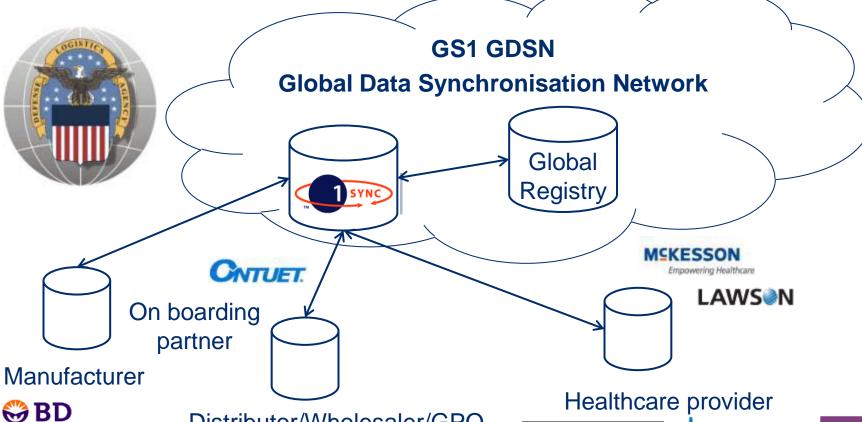
Data Synchronisation & Product Classification for Healthcare





US Department of Defense

Pilot (2007)



















Ascension







Healthcare 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



Healthcare Australia's GDSN rollout



The National Product Catalogue

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



e-health

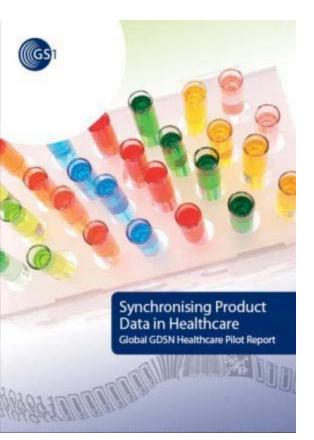


Healthcare Global GDSN Pilot (2008)





Healthcare 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

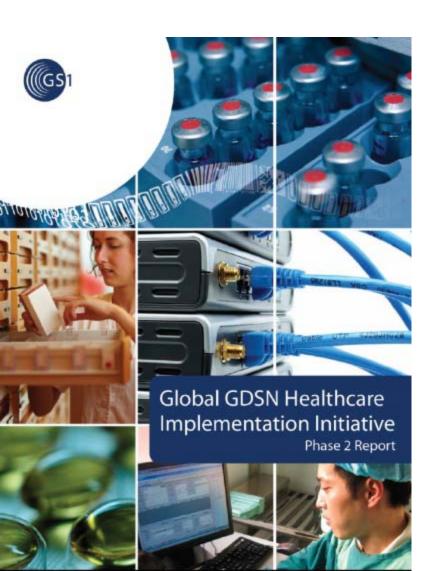
Shelf Life From Production

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



- 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



This Week:

- Wednesday, 11:00 12:30 (breakout session)
 Roundtable discussion group
 - Electronic product catalogues, UDI databases and the GDSN:
 Making it work



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





- Background
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Healthcare Traceability in Healthcare

"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



Healthcare 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



Healthcare Regulatory compliance (cont'd)



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...



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Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production¹ to Point of Use²

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (Al, e.g. Serial No. Al(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
- The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)... SO THAT:

The terms use or used can also mean consumed, infused, implanted, destroyed

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Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production¹ to Point of Use²

SO THAT:

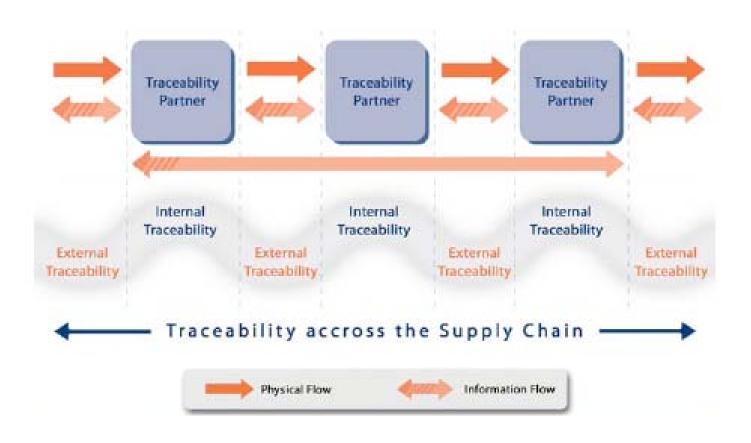
- Items can be tracked (forward / downstream) across the entire supply chain (production to use) in real time on demand
- Items can be traced (backward / upstream) across the entire supply chain (from current location back to the producer) in real time on demand
- Patients Electronic Health Records (EHRs) 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)...

The terms use or used can also mean consumed, infused, implanted, destroyed



Traceability across the supply chain



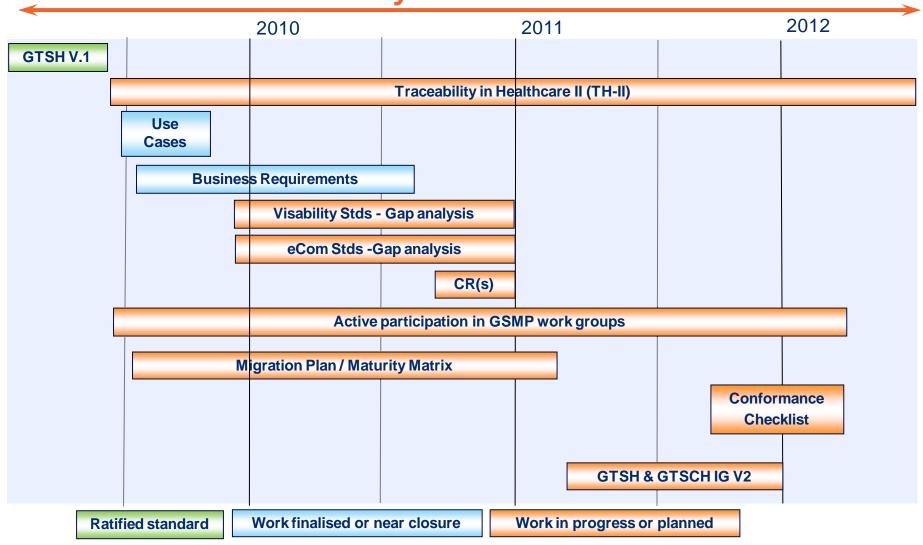


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Healthcare Roadmap to global standards

Global Traceability Standards for Healthcare







Global Traceability Standard for Healthcare

Business process and system requirements for supply chain traceability

Business Process and System Requirements for Supply Chain Traceability

Global Traceability Standard for Healthcare

Issue 1.0.0. Feb-2009

Published 27 February 2009



GS1 Standards Document

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

GS1 Global Traceability Standard for Healthcare (GTSH) Implementation Guide

Issue 1, April-2009

Published 24 April 2009

Available at www.gs1.org





Healthcare Traceability – a business process



Global Traceability Standard for Healthcare (GTSH)

A Process Standard enabled by the GS1 System of Standards

And GTSH Implementation Guideline

✓ 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

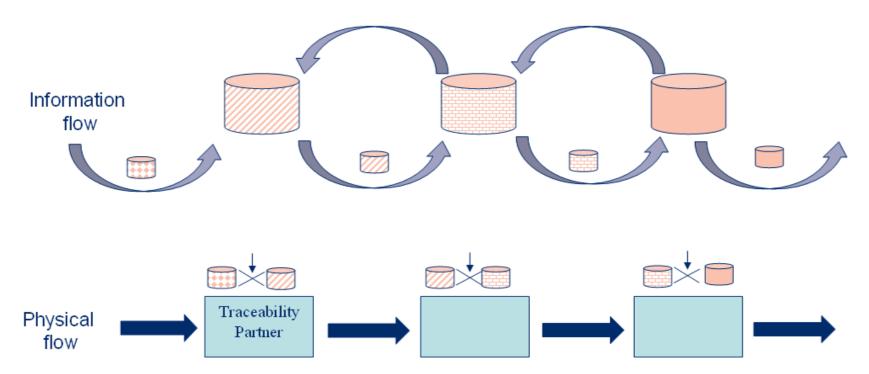
✓ Data communication

- Associate the physical flow of products with the information flow
- Different information sharing models

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

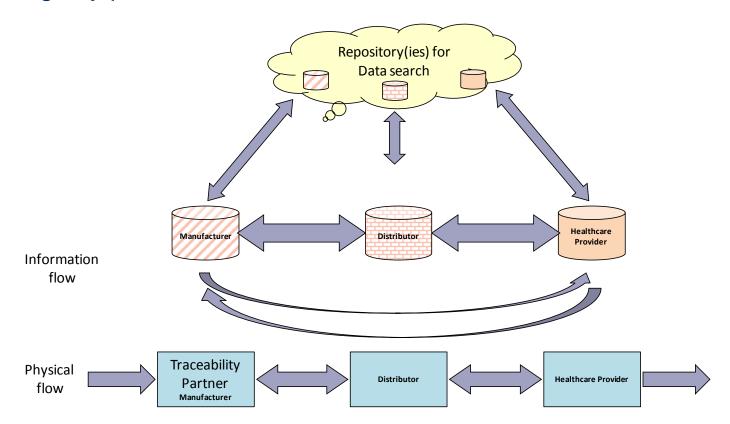




Healthcare Information Sharing Model 4

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.





Healthcare 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



TH-II - Where we are now...

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
 - BRs accepted

GS1 System

Traceability

in Healthcare I (TH-I) Focus:

- 3. Technical Gap Analysis underway
- 2. Product Identifier Authentication
 - 1. BRAD in development
- Product Recall



- Background
- Where we are going
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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...



- 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"...



Healthcare Traceability session this week

This Week:

- Thursday, 11:00 12:30 (breakout session)
 Roundtable discussion group
 - Traceability in Healthcare: Which model?



Global teams

Global TH-II Team - Product Identifier Authentication

Local teams

Contact your local Member Organisation representative





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