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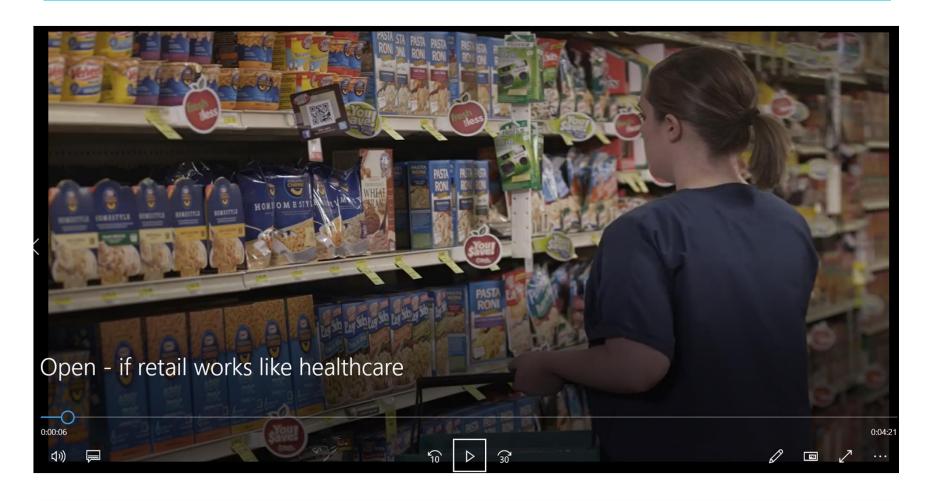
## GS1 Standards use in the Healthcare Supply Chain

Andy Siow, Manager, Technical Standards & Services GS1 Singapore 21 August 2019



### If Retail Works Like Healthcare







### **Presentation Outline**



- Introduction to GS1 in Healthcare
- Overview of GS1 System of Standards
- New GS1 Standards Updates
  - GS1 Clinical Standards
  - GS1 Digital Link Standards
- Global Trend in Pharma & Medical Device Identifications
- Overview of Regulatory Requirement Landscape



### Introduction to GS1 in Healthcare



### GS1 by the numbers



Neutral and not-for-profit

User-driven and governed

Global and local

Inclusive and collaborative

#### GS1 is most widely used open standards for SCM

#### **GS1** Healthcare Mission:

....

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing patient safety, operational and supply chain efficiencies

#### 1 million

150 countries

5 billion

**114 MOs** 

over 1 million companies worldwide use GS1 standards 25 industries served across 150 countries

Barcodes scanned more than 5 billion times per day globally 114 Member Organisations around the world



### GS1 is a Standards Development Organisation working with others



The council is form to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps and counter-productive standardization effort.

















International Organisation for Standardisation

European Committee for Standardization Health Level 7

International International Health Terminology SDO

Clinical Data Interchange Standards Consortium

Integrating the Healthcare Enterprise

Digital Imaging and Communications in Medicine





















World World Health Customs Organization Organization

International Federation

International Council for Commonality in Blood Banking

Automation

International Society for Quality in Healthcare

European Association of Hospital **Pharmacists** 

European Federation of **Pharmaceutical** Industries and Associations

European Association of Medical device and diagnostics industry





### GS1 Healthcare: an expanding, committed community of globally engaged stakeholders...





...and there are many more companies working with GS1 at a local level



## Value Proposition for Solution/Logistic Service Providers working with GS1



Wide adoption of GS1
Standards in Healthcare in more than 70 countries

To meet healthcare clients' needs by implementing their requirements



Provide solution which facilitates interoperability both intra & inter enterprise connectivity

Become a healthcare industry though leader

https://solution-providers.gs1.org/

and more benefits....



## ...as well as with leading hospitals and government agencies to implement GS1













**Australian Government** 

Australian Digital Health Agency







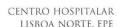






































UNIVERSITÄTSKLINIKUM Schleswig-Holstein





























## Endorsement paper - Healthcare leaders endorsing GS1 Standards



- GS1 standards enable streamlined supply chain processes and improve visibility – from manufacturers to patients
- Global healthcare leaders have endorsed the GS1 Healthcare standards and the number is growing.
- Endorsement paper could be found on :
   <a href="http://www.gs1.org/sites/default/files/docs/healthcare/endorsement">http://www.gs1.org/sites/default/files/docs/healthcare/endorsement</a>
   paper-hd.pdf



















































## Why are standardisation important for Healthcare?



## Lack of standards in daily life is inefficient and annoying...





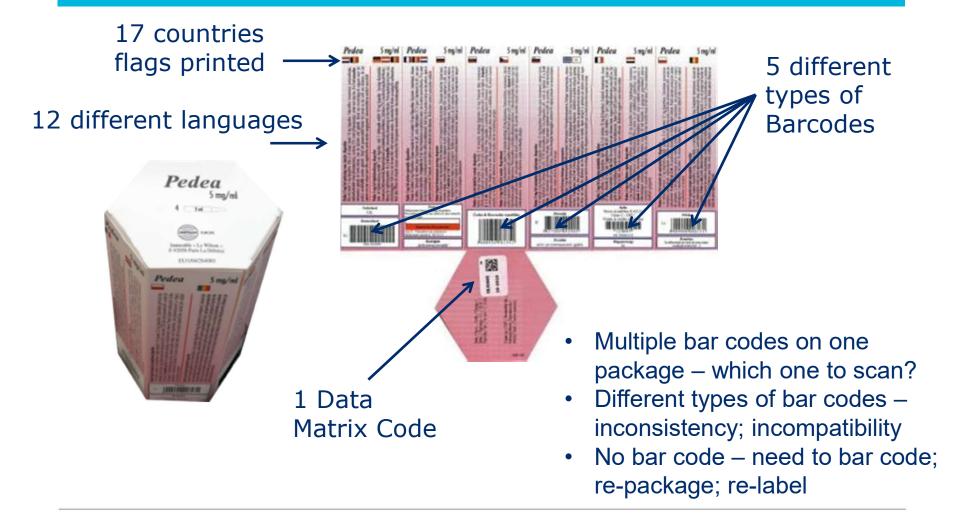


### Standardization came too late



## ..in Healthcare it is dangerous and inefficient!







## The Need for Global standards in Healthcare (Upstream)





#### "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

## Why using local formats/national codes are not ideal (Downstream)



#### Some observations in hospital environment

#### GOOD

- Barcode scanning are widely implemented in various parts of hospital processes. Easy to use.
- Pharmacists and nurses prefer to receive "barcode" ready products as it makes their work and processes simpler.
- Hospitals are investing and implementing various systems to automate processes.

#### Not so good

- Non-standardisation of product code. We noticed at least 4-5 different formats of product codes used. (Such as: GTIN, GPO No., SIN No., Hospital Internal No.)
- Some systems are able to process GS1 barcode, some are not.

Using your own local format introduces cost, increases the risk of error and overall inefficiency.



# Potential issues with non-standards product code in Healthcare Provider Environment (Downstream)



Create Inefficiency, increases risk & additional Cost in following areas:

- Manual stock received process
- Error prone to data entry
- Need for re-label work
- System mapping
- Medication Error
- Lack supply chain visibility. JCI audit requirement.
- Breakage in link management impact of capability for effective product traceability & recall
- System may not be able to interoperability/prevent from sharing distribution data with other institutions
- Manufacturers/distributors are not able to leverage on existing standards cater for global market for specific local needs





### GS1: Area of focus in Healthcare





One of these medicines is fake. Can you tell which?











## Strength in unity: The promise of Global Standards in healthcare" (McKinsey 2012)



- "Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities"
- "Rolling out such standards-based systems globally could prevent tens of millions of dollars' worth of counterfeit drugs from entering the legitimate supply chain"
- [We] "estimate that healthcare cost could be reduced by \$40 billion-\$100 billion globally" from the implementation of global standards
- "Adopting a single set of global standards will cost significantly less than two" (between 10-25% less cost to stakeholders)

SOURCE: McKinsey report, "Strength in unity: The promise of global standards in healthcare", October 2012



## Standards Comparison Grid (McKinsey 2012)



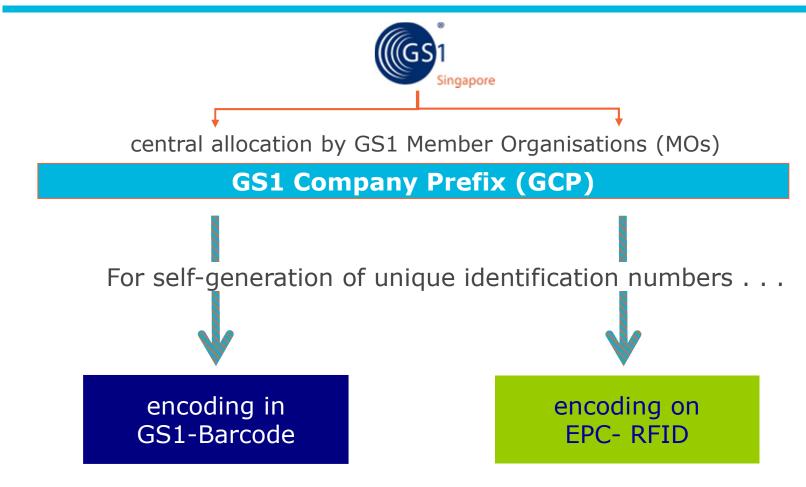
	GS1 Standards	HIBCC Standards	National codes
Availability of high information density data carriers	Yes (GS1 DataMatrix and RFID)	Yes (3 ISO 2D Matrix and RFID)	Generally not (linear barcodes)
Comprehensiveness of the standar in terms of identification definitions	10 identification keys (incl. GTIN, GLN)	Product (UPN), location (HIN)	Product code only
Master data synchronization	GDSN (Global network)	UPN repository	No
Includes traceability standard	Global Traceability Standard for healthcare	No	No
Interoperability with national ID numbers	National numbers compatible with use of GS1 standards	Not applicable - no national codes for medi- cal devices	Not intended to be used outside country
Used in all global geographies	Yes	Yes, except Japan	Only in country
Span across product types	Pharmaceuticals and medical devices	Medical devices (pharmaceuticals in The Netherlands)	Pharmaceuticals only
Global organization infrastructure and support	Global infastructure and support (global office and 111 member orgs)	US; support staff in Aus- tralia and Europe	Within relevant country
Additional industry coverage	Core sectors in Retail, Healthcare, Transport and Logistics; 20 others	Healthcare only	Pharmaceuticals only
Regulatory agencies / jurisdictions accepting use of standard	65	Turkey only	China, Germany, Italy, Belgium, Portugal

### Understanding GS1 Standards



### How to get started with GS1?

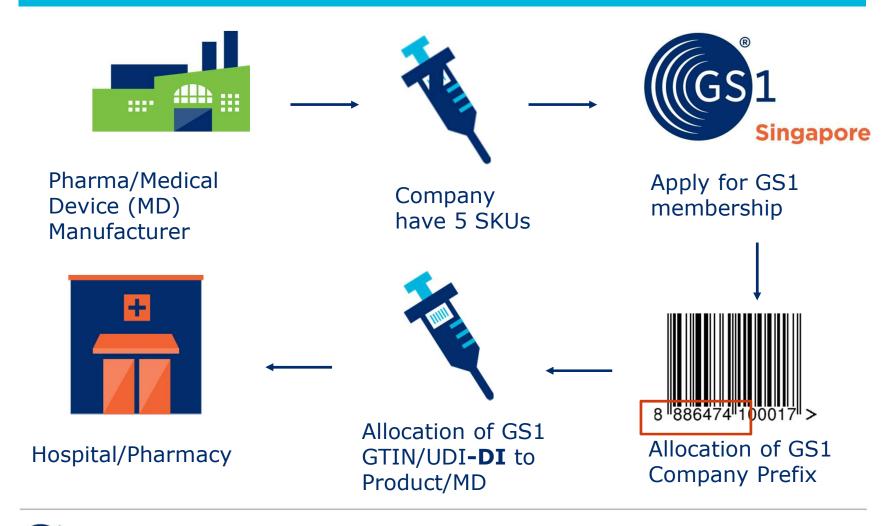






## GS1 GTIN/UDI**-DI** Issuing Process (Example)

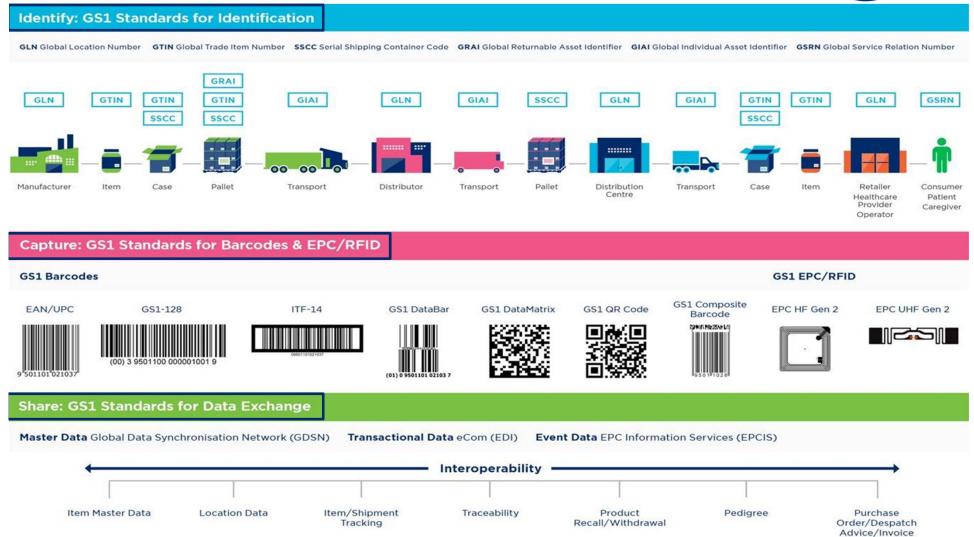






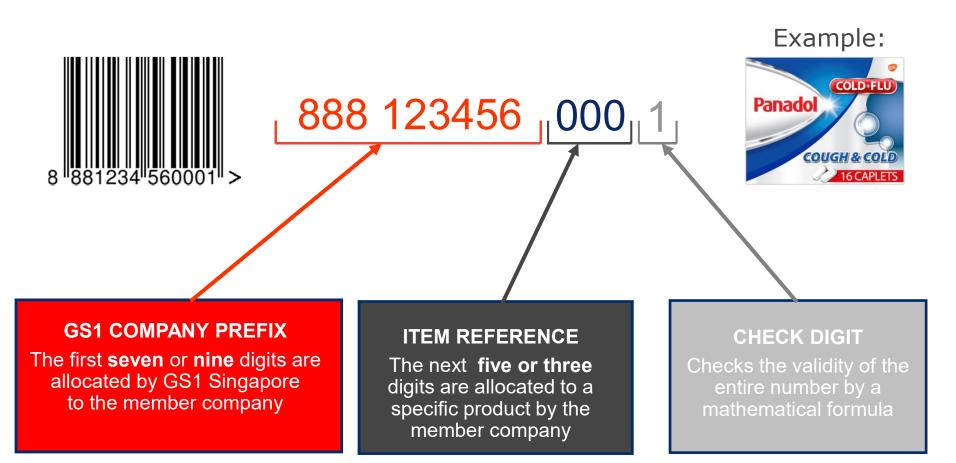
### **GS1** System Of Standards





## Identify & Capture Example: Structure GTIN-13 (Barcode)

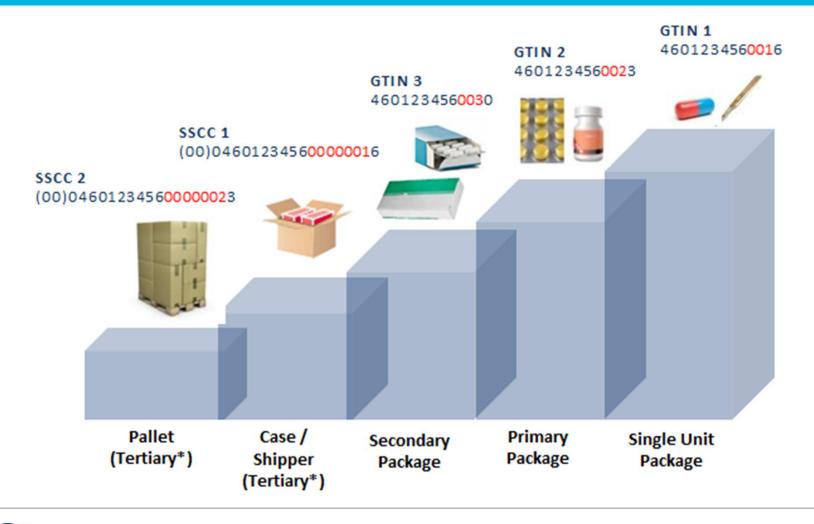






### **Product Hierarchy**







### Allocation of GTIN's...

...fundamentals still apply...

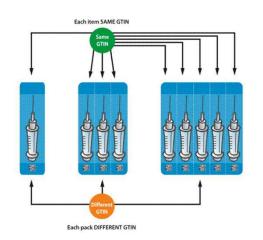
#### GS1 Healthcare GTIN Allocation Rules

GLIN Allocation Rules for the Healthcare Sector.

embrace serve, sourcline, buly overs







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!

http://www.gs1.org/docs/gsmp/healthcare/GS1 Healthcare GTIN Allocation Rules.pdf







### GS1 Gen Spec includes 100+ "Application Identifiers" a.k.a. "Key Attributes"

#### Application Identifiers generally or commonly found in Healthcare

phile	acion facilities	generally of c	ommonly re
00	SSCC (Serial Shipping Container Code)		
01	GTIN (Global Trade Item Number		
10	Lot / Batch	GS1-128	
11	Production	001-120	
17	Expiry Date		
21	Serial Number		
710	NHRN - Germany PZN	(01)04601234	567893(17)16012
711	NHRN - France CIP	(02) 01002201	
712	NHRN - Spain CN		GS1 DA
713	NHRN – Brazil DRN		
7003	Expiry Date + Time		F6
7004	Active Potency		
8003	GRAI (Global Returnable Assets Identifier)		
8004	GIAI (Global Individual Assets Identifier)		
8017	GSRN Service Provider	(01)	
8018	GSRN Service Recipient	(17) (10)	

Service Relationship Instance Number

#### **GS1 DATAMATRIX**



(01)04601234567893 (17)160125 (10)ABC123 (21)123456789



8019



### **GS1** Data Exchange Standards

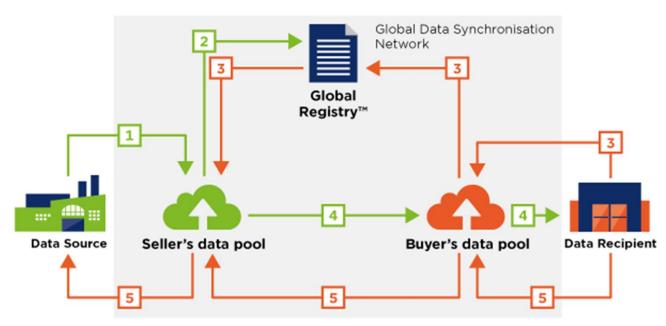
The Global Language of Business



## Data Exchange Standards: GDSN(Master Data)



GS1 Global Data Synchronisation Network® (GDSN) is a network of interoperable data pools enabling collaborating users to securely synchronise master data based on GS1 Standards.



- 1. Loading of company data
- 4. Publishing of company data
- 2. Registering of company data
- Confirmation of receipt of company
- 3. Subscription to seller's data pool

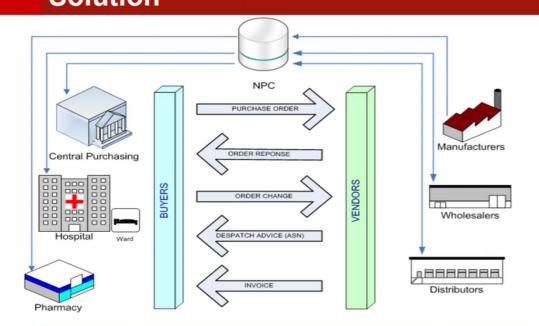


# The National E-Health Transition Authority (NEHTA) uses GDSN to support their eProcurement processes.



NPC and the NEHTA eProcurement Solution

eProcurement message flow using NPC







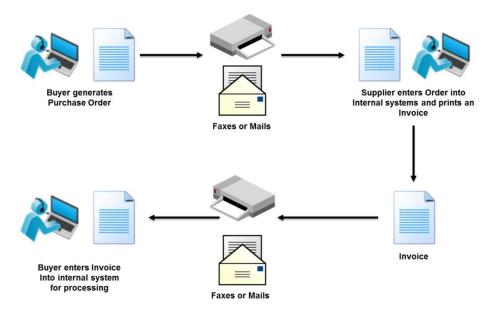


### Share: Data Exchange Standards GS1 EDI (Transaction Data)



Electronic Data Interchange (EDI) is the computer-to-computer exchange of business documents in a standard electronic format between business partners.

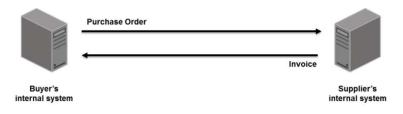
#### Manual Process



people involved

Lots of paper and

**EDI Process** 



No paper, no people involved



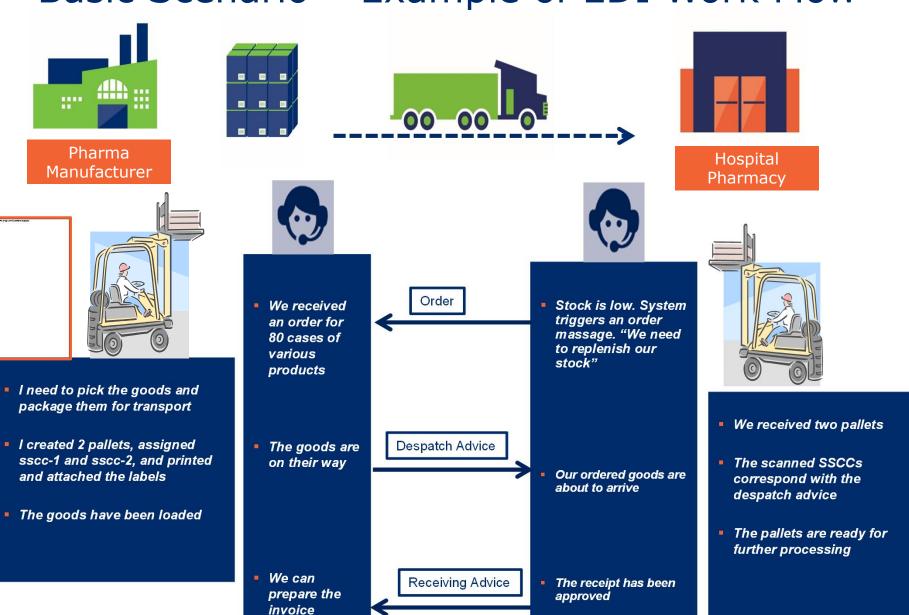
#### Standard format required

#### **GS1** EDI covers:

- Master Data Alignment
- Order & Delivery
- Financial Settlement
- Transport & Warehouse **Management**

Sources: edibasics

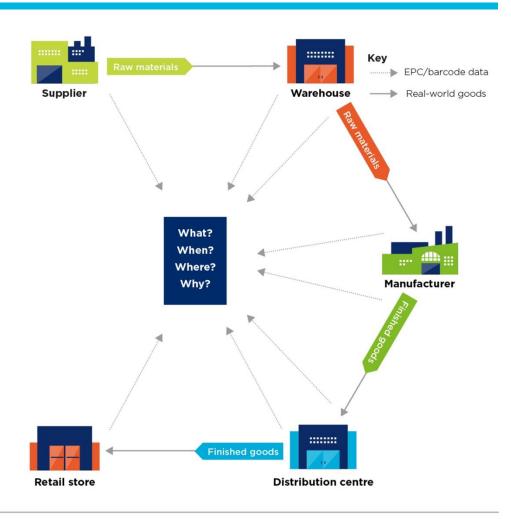
### Basic Scenario - Example of EDI Work Flow



## Data Exchange Standards: EPCIS (Event Data)



that enables trading partners to **share information about the physical movement and status of products** as they travel throughout the supply chain – from business to business and ultimately to consumers.

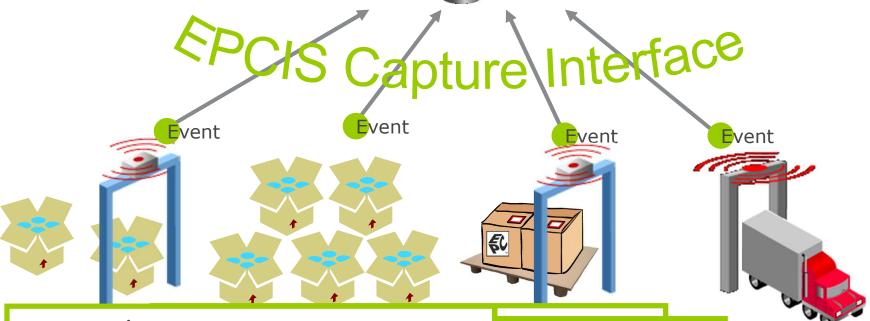




### EPCIS Capture of supply chain events







#### **AggregationEvent**

SSCC 4001356.5900000817 WHAT:

SGTIN 4026800.010421.101

SGTIN 4026800.010421.102

WHERE: SGLN 4012345.00040.0

WHEN: 23.10.2009 13:40:00 UTC+1

WHY: commissioning

yEvent GTIN 4026800.010421

5

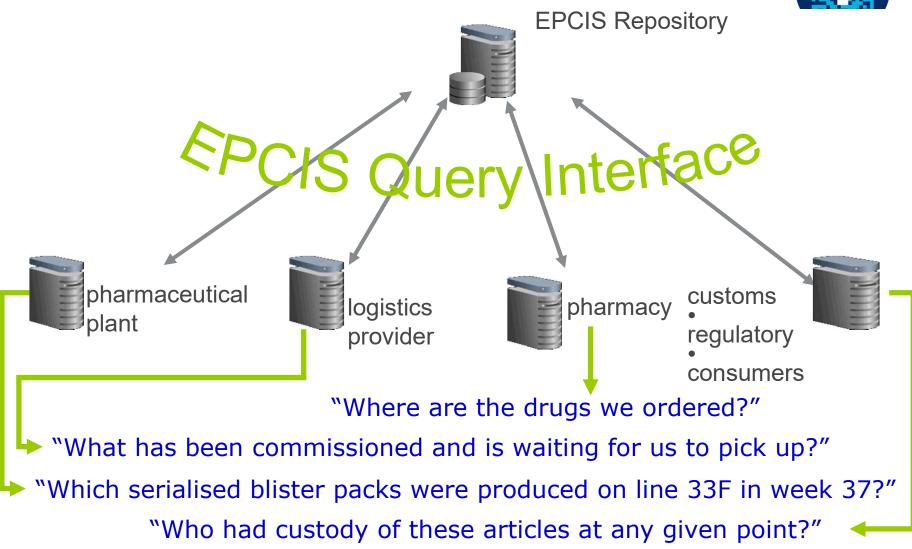
SGLN 4012345.00031.0

2.10.2009 11:20:00 UTC+1

Source: Craig of GS1

#### EPCIS query of supply chain events







© GS1 2019

## Introducing New GS1 Standards

- GS1 Clinical Trial Standards
- GS1 Digital Link Standards



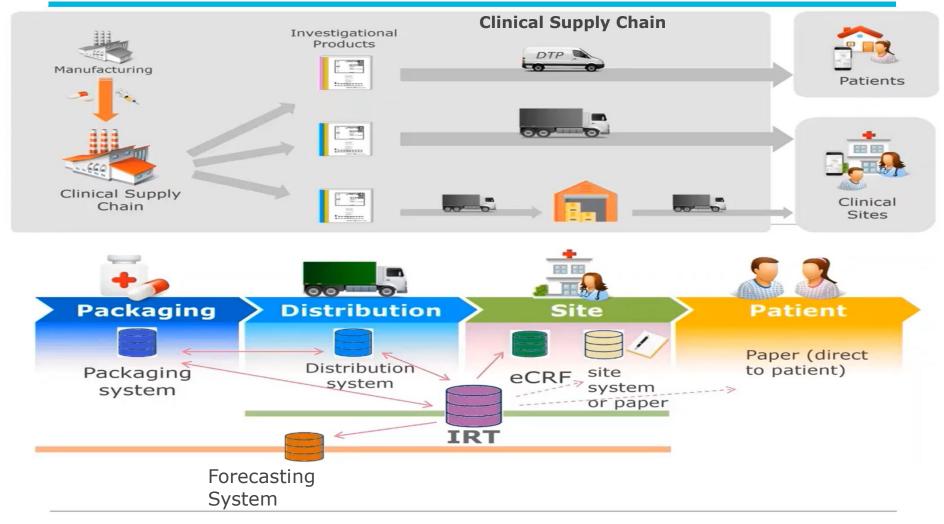
### **GS1** Clinical Trial Standards

Why globally standardised identifiers and barcodes for investigational products?



## IP is tracked in multiple system across the supply chain







## Current paper IP management example



	nment Request		,	
Protocol number	AND ADDRESS OF THE PARTY AND PARTY.	IVRS Name:	-	
Date/Time of die Country:	spatch: 09.01.2017 15:30 France	Telephone:	+1 415 293 1353	
CRTN number:	France	Web:	-	de la constant
Investigator:	CH Victor Dupouy			
	Pharmacie / Secteur Essais			
Attention:	Olivia Chauvel			
Shipping addr	ss: 69 rue du Lieutenant Color	el		
	FR-95107 Argenteuil			
Shipping phone				
Shipping fax:	-			
Consignment n				
Type of supply:	RE-SUPPLY			
Delivery No.:				Page 1 /
Item code	Item name			Tot
L	Medication/ Batch number	Use by date	Quantity	
	1 vial 500mg/10mL or Plcbo			1
	WCC00302 /	31.10.2017	1	
	WCC00885 /	31.10.2017	1	
	WCC10047 /	31.10.2017	1	
WCC10247 / WCC10220 /		31.10.2017	1	
	WCC10220 -	31.10.2017	1	
		31.10.2017	1	
	WCC16333		1	
	WCC16333 /			
	WCC21322 /	31.10.2017	1	
	WCC21322 / WCC21918	31.10.2017 31.10.2017	1	
	WCC21322 / WCC21918 WCC22370	31.10.2017 31.10.2017 31.10.2017	1 1 1	
	WCC21322 WCC21918 WCC22370 WCC25969	31.10.2017 31.10.2017 31.10.2017 31.10.2017	1 1 1	
	WCC21322 / WCC21918 WCC22370	31.10.2017 31.10.2017 31.10.2017	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	

From the delivery form...

To the inventory log





Source: Presentation from CH Victor Dupouy and Sanofi, February 2019

## Examples of current situation







Numbered boxes and bottles





Multiple barcodes







## What has been developed?



### A global standard by the industry

resulting from an industry-led working group:

An industry-led effort

Global standards unique to clinical trial products

An element of trust

#### **GS1 Clinical Trial Standards**





### **GS1** Clinical Trial Standards







## Standardisation along the Clinical Supply Chain



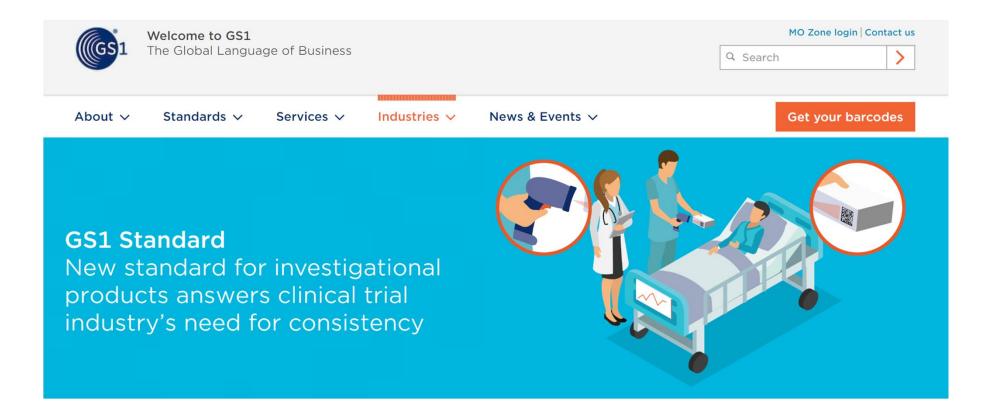
**Efficiency Process Familiarity Safety** Accuracy **Label & Pack Design Packaging Operations** Standardization of Clinical Labels and information Ease In line Controls. Distribution Identification of kits / Sub batches Contractors 魕 Shipments preparation are more reliable Hospital Supply Chain stakeholders are sharing and Sub-Contractors exchanging information Ease Study Management **PharmaB Patient** activities at site level · Connectivity to Patient's ecosystem (smartphones, diaries...) · Innovative Solutions (eLabeling...) Pharma C

#### **Providing an element of Trust**



### Visit GS1 Clinical Trial Info Page





https://www.gs1.org/industries/healthcare/clinical-trials



## GS1 Digital Link Standards

For Healthcare (eleaflet)



### **GS1** Digital Link



## A single barcode for identification, authentication and access to information for medical products





#### How it works?



MoH



8881234567895

Converts the data elements into a URI

https://example.com/gtin/8881234567895





(01)08881234567895(17)200400(10)DZ929

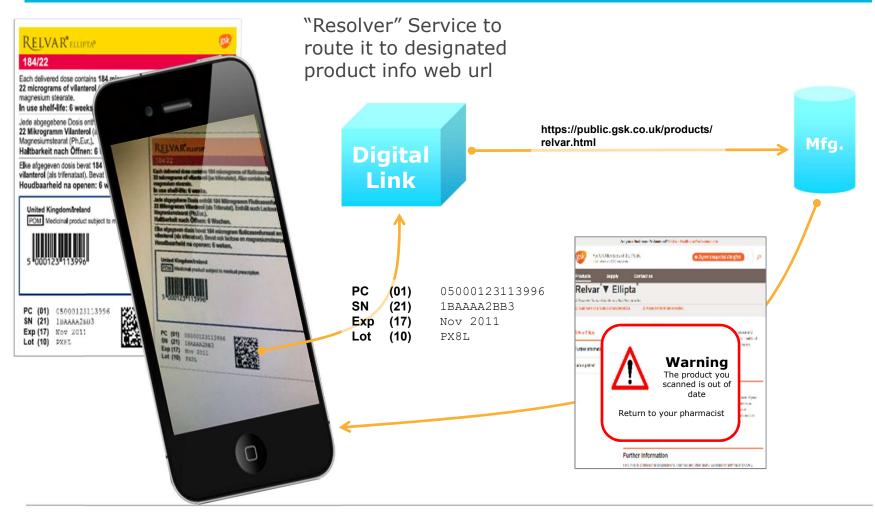
Converts the data elements into a URI

https://example.com/gtin/08881234567895/lot/DZ929?exp=200400



## Extra services can be offered using the scanned data







50

## Potential to route different users to different end points and sources of content





(GS<sub>1</sub>

51

### GS1 Digital Link eLeaflet Demo





Scan

<u>Perjeta 420 mg/14 ml</u> <u>concentrate for solution for</u> <u>infusion</u> (07640149612837)



#### Perjeta 420 mg/14 ml concentrate for solution for infusion

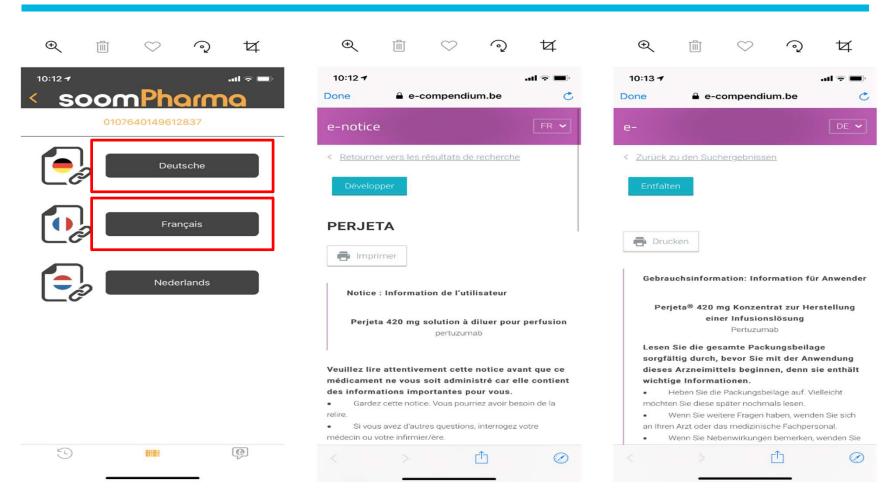
# https://id.gs1.org/01/07640149612837 https://id.gs1.org/01/07640149612837/ epil de ePIL (DE) https://www.e-compendium.be/de/packungsbeilagen/patient/3570/3021 fr ePIL (FR) https://www.e-compendium.be/fr/packungsbeilagen/patient/3570/3021 nl ePL (NL) https://www.e-compendium.be/nl/packungsbeilagen/patient/3570/3021





### GS1 Digital Link eLeaflet Demo







## Calling for Pilot (Participation) GS1 Digital Link + eLeaflet



Looking for interested parties (Pharma or Medical Device) companies whom wish to pilot using GS1 Digital Link Standards for eLeaflet initiatives.



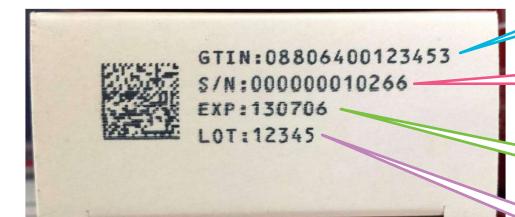
## The Global Trends in Pharmaceutical and Medical Device Identification



## Global Trend 1: IDENTIFY 4 Identification Attributes







Serial Number

**Expiry Date** 

GTINs (Global Trade Item Numbers) provide access to information held in computer files – they are unique — non-significant — international — foundational.

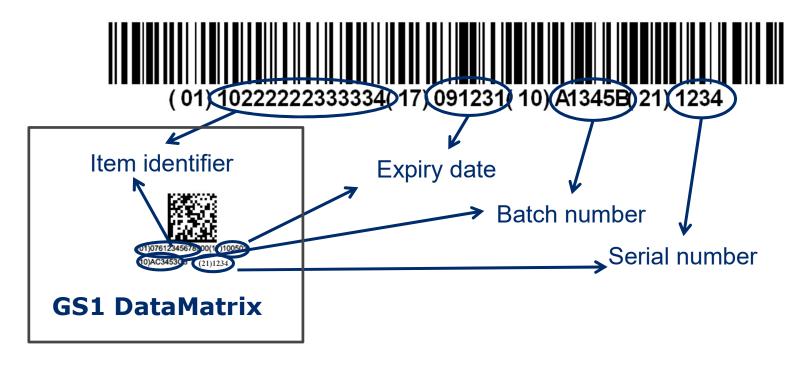
Lot/Batch number



## Global Trend 2: Data Carriers Use of GS1 DataMatrix



**GS1-128** 





## Global Trend 3: Share Need for Traceability





## Regulatory Requirement Overview



## Pharmaceutical Regulatory Requirements



#### **2 Major Markets:**

- US DSCSA (Drug Supply Chain Security Act)
  - over a period of 10 years by providing a migratory path from lot identification to serialisation to item-level traceability. (2013 to 2023)
- EU FMD (Falsified Medicine Directive)
  - ensure product integrity and authentication of medicines (ie. safety features and product serialisation) by Feb 2019. Set up end-to-end verification system" for drugs across the world.

#### **Recent developments**

- China
- Russia
- South Africa
- Middle East
  - · Bahrain, Lebanon, Oman, UAE, Jordan, Sandi Arabia ..etc

PC: 09876543210982

SN: 12345AZRQF1234567890

NN: (optional)
Batch: A1C2E3G4I5

Expiry: 180531



### US DSCSA implementation phases



#### Lot-level management

Started on January 1, 2015 for manufacturers, wholesalers, and repackagers, and July 1, 2015 for pharmacy (hospitals and retail): Share the 3T's: Transaction Information (TI), History (TH), and Statements (TS) at the Lot (or Batch) level of identification.

#### **Item serialization**

Mid-term (2017–2019): Manufacturer/repackagers serialize packages of drug products using a product identifier (GS1 Global Trade Item Number® (GTIN®) or NDC), serial number, lot number, and expiration date.

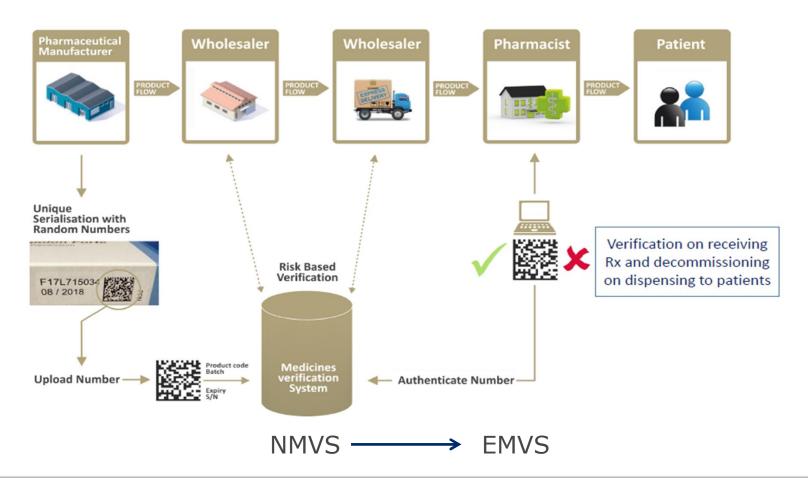
#### **Serialized item-level traceability**

By November (2023), make available information that would allow supply chain partners to trace the ownership back to the initial manufacturer or repackager.



## EU Traceability Concept: Point of Dispense Verification







## Korea Serialisation System based on GS1 Standards



 $\leftarrow$ 

## Korea Pharmaceutical Serialization System





### Medical Devices Regulations





The **U.S. FDA** released, in **September 2013** a rule which establishes that a common, worldwide system for product identification should be applied to all medical devices placed on the U.S. market.

The rule establishes that:

- a unique device identifier number should be assigned by the device manufacturer to each version or model of a device.
- the unique device identifier should be both in human readable format and in AutoID format. By default, this information will be applied on the label of each device uniquely identified.



The **EU Medical Device Regulation (MDR)** and In-vitro Diagnostic Regulation **(IVDR)** have been adopted on **25 April 2017** and define the requirements for the EU UDI system.

According to the Regulations, a UDI number must be applied to the medical device label, its packaging and, in some cases, the device itself.

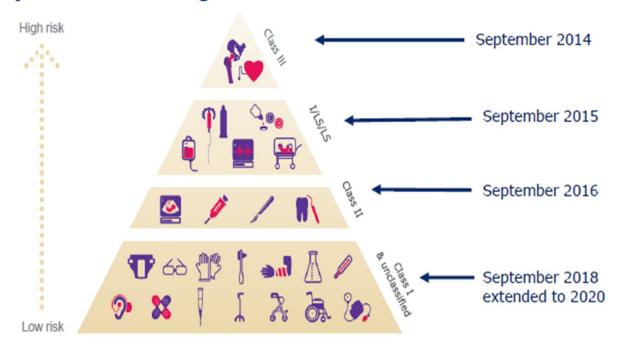


## US regulation implementation planning



The regulation was voted on 24 September 2013

#### Database (GUDID) + UDI marking deadlines:



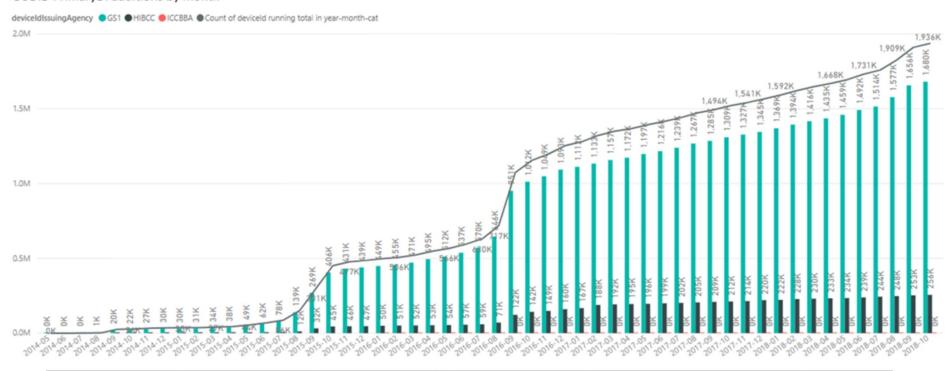
2-year additional period granted for direct marking



### Total Number of Primary Device Identifiers Listed in the FDA GUDID by Issuing Agency



#### GUDID PrimaryDI additions by month

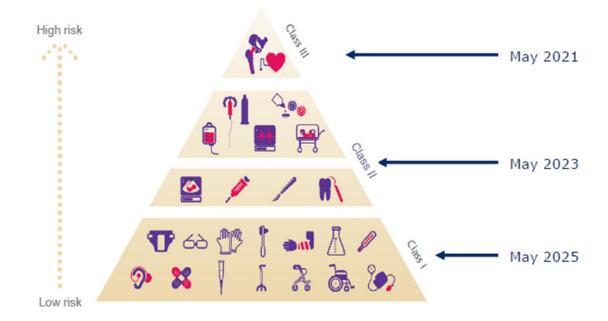




## EU regulation implementation planning



- 1. Database (EUDAMED) + UDI-DI assignement : 26 May 2020
- 2. Marking deadlines:



2-year additional period granted for direct marking

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746



<sup>\*</sup>In-Vitro diagnostic devices have different deadlines for implementation. See the related regulation:

#### PRESS RELEASE

## GS1 has been designated as issuing entity for Unique Device Identification (UDI) by the European Commission

**FOR IMMEDIATE RELEASE – Brussels, 7 June 2019.** GS1, the leading global supply chain standards organization, has been <u>designated by the European Commission</u> as issuing entity for Unique Device Identifiers (UDIs). GS1 global standards meet the EU Commission's criteria for the issuance of UDIs, supporting the EU regulators in ensuring a successful implementation of the UDI system as defined by the EU Medical Device Regulation and In-Vitro Diagnostics Medical Devices Regulation (<u>EU Regulations</u>), and enabling manufacturers to comply with these requirements.

The UDI system intends to provide a globally harmonised framework for identification of medical devices to enhance quality of care, patient safety and business processes.

"The GS1 global system of standards is the most widely implemented in the world and is used by all stakeholders in healthcare supply chains. The GS1 identifiers are fundamental to enable an efficient and effective identification of medical devices from product conception through every step of the supply chain lifecycle. Strengthening patient safety is central to GS1's mission in healthcare and GS1 is committed to support the EU Commission, manufacturers and other stakeholders worldwide in implementing the new EU UDI system." said Miguel Lopera, President and CEO of GS1, which has headquarters in Brussels, Belgium.

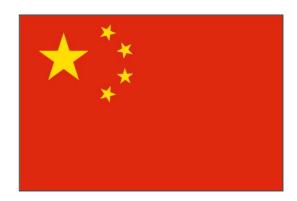
Since 2013, GS1 is accredited as UDI issuing agency in the U.S.A. and other regulators are also planning to allow the use of GS1 standards as the basis of their national UDI system.

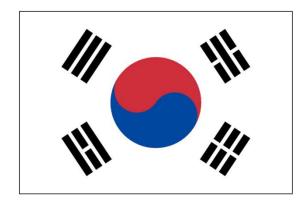


## Recent Country UDI Development









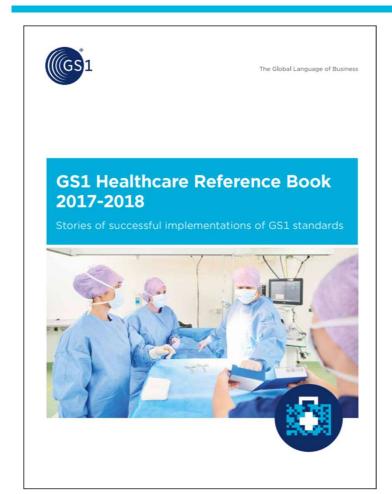




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#### GS1 Healthcare Reference Book





## Compilation of healthcare success stories

Reference Book 2018/2019 NEW!

Reference Book 2017/2018

Reference Book 2016/2017

Reference Book 2015/2016

Reference Book 2014/2015

Reference Book 2013/2014

Reference Book GS1 Argentina

"Successful cases of Traceability in

the Healthcare Sector in Argentina"

Reference Book 2012/2013

Reference Book 2011/2012

Reference Book 2010/2011

Reference Book 2009/2010



#### **GS1** Healthcare Webinars Series



#### Bedside scanning requires cultural change



"When implementing bedside scanning it is important to be a clear leader and show the way. However, it is equally important to have strong nurses on the floor as ambassadors to help pave the way. A cultural change must make sense for the individual nurse in order to succeed, and it is a process that needs to be kept in focus."

Trine Spiegelhauer is a Registered Nurse and Nursing Director for the Clinic for Children and Adolescents with Surgical Diseases at Rigshospitalet Nursing School, Copenhagen, Denmark.

During this webinar 'Bedside scanning requires cultural change' Trine will present:

- 1. Implementing barcode scanning is not something you do overnight;
- 2. the importance of leadership;
- 3. and the necessity to have software and hardware up to date.

Thursday 29 August 2019

Brussels, CET: 14:30 - 15:30 New York: EST: 08:30 - 09:30 London, GMT: 12:30 - 13:30 Singapore, SGT: 20:30 - 21:30 São Paulo, BRST: 10:30 - 11:30

https://www.gs1.org/healthcare/hpac webinars



### Upcoming Event: 36<sup>th</sup> Global GS1 Healthcare Conference 5-7 November 2019, New Delhi, India



With a focus on **patient safety**, the conference themes include:

- Track and trace for access to safe medicines
- Hospitals working towards a better quality of care and increased efficiency
- Unique Device Identification (UDI)





\*Participation free for regulatory bodies and hospitals

More details, please visit:

https://healthcare-event.gs1.org/



## GS1 Implementation in NHS Trust Hospital







### **Contact Details**

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