

The Global Language of Business

GS1 standards Primer session

29th Global GS1 Healthcare conference Dubai, United Arab Emirates







GS1 Healthcare, the global perspective

Anouk Chavel, Global Marketing Lead, GS1 Global Office



Agenda of the session



- 1. GS1 Healthcare, the global perspective
- 2. Automatic Identification Data Capture
- 3. Patient and care provider Identification
- 4. Master Data Management and Global Location Numbers
- 5. EPCIS
- 6. Electronic Data Interchange (EDI)

Anouk Chavel Chuck Biss Christian Hay Pete Alvarez Craig-Alan Repec Tania Snioch



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GS1, most widely used standards





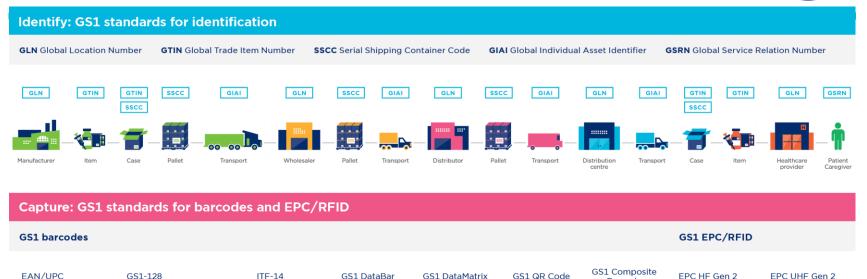
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(10)AC3453G3





GS1 ensures end-to-end visibility in the supply chain









GS1 DataBar



GS1 DataMatrix







Barcode

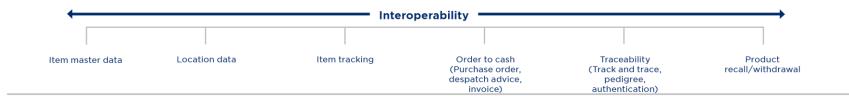


EPC HF Gen 2



Share: GS1 standards for data exchange

Master data GLN Registry for Healthcare®, Global Data Synchronisation Network (GDSN) Transaction data GS1 EDI Visibility event data EPC Information Services (EPCIS)

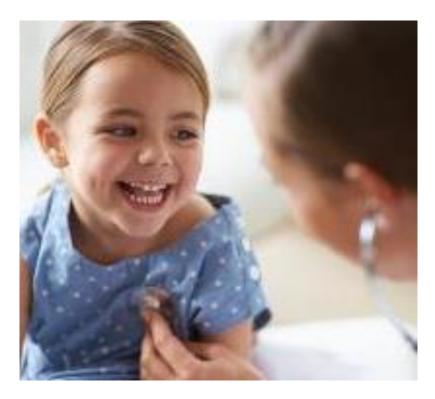








Patient safety



Lower costs









GS1 is a neutral not-for-profit organisation driven by its users, that facilitates collaboration amongst trading partners, to create more efficient, safer and sustainable value chains through global standards.



Global reach, local presence





112 Member Organisations More than 1,000,000 member companies 150 countries served 2,000 + employees





The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for





GS1 Healthcare - Voluntary, Global



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





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



...as well as with leading healthcare providers to implement...







...working together with GS1 Member Organisation (MO) User Groups in 38 countries





...and with many more MOs engaged in healthcare





...and with global organisations...







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Automatic Identification and Data Capture in Healthcare ...an AIDC short course

Chuck Biss, Senior Director, ADIC Healthcare, GS1 Global Office



GS1 standards





GS1 standards for identifying, capturing, and sharing information about products, business locations, and more—make it possible for companies to speak the same language, connect with each other and move their business forward.



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 that data** directly into computer systems (i.e., without human involvement)."

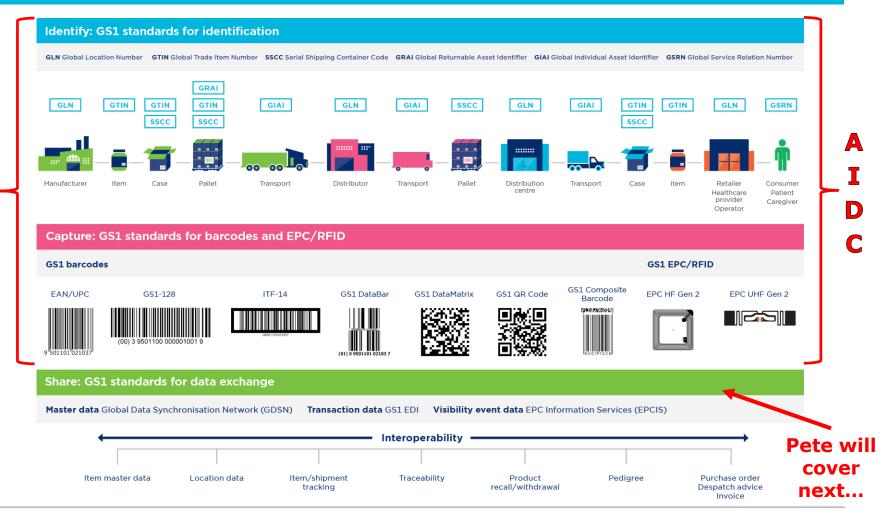
Wikipedia, 2009





GS1 standards... and AIDC







Α

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С



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...





Scope - All healthcare products...



Pharma / Vaccine / Nutritional



Retail





Non-retail

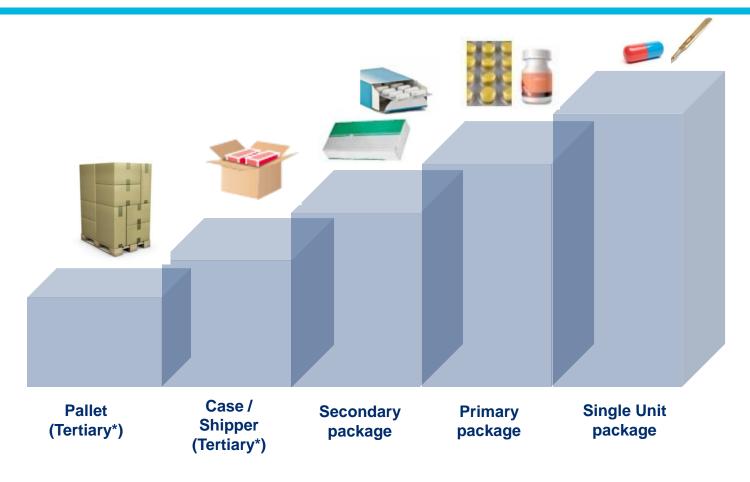






Scope – ID at all packaging levels...





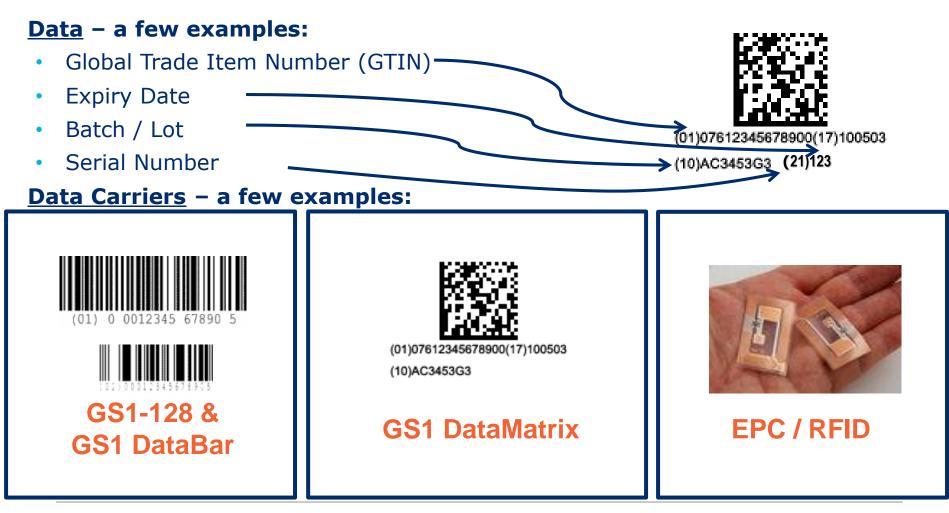
NOTE: * - Potentially a new definiton that is needed...



Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

Scope - Data & Data Carriers...









GS1 Identification Keys

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





GS1 Identification Keys...



000 20 Item identifier = **GTIN** Unique Global Trade Item Number Non-significant • International • Logistics unit Secure SSCC identifier = 581 Foundational Serial Shipping Container Code Location identifier = **GLN** Global Location Number

...and there are more ...



...but sometimes there is need to capture data beyond basic item ID...









The GS1 General Specification includes 100+ "Application Identifiers" ("Key Attributes" or "AI's") for various use cases & various sectors

..however the Application Identifiers <u>most commonly used at</u> <u>this time</u> (in various combinations) in Healthcare are:

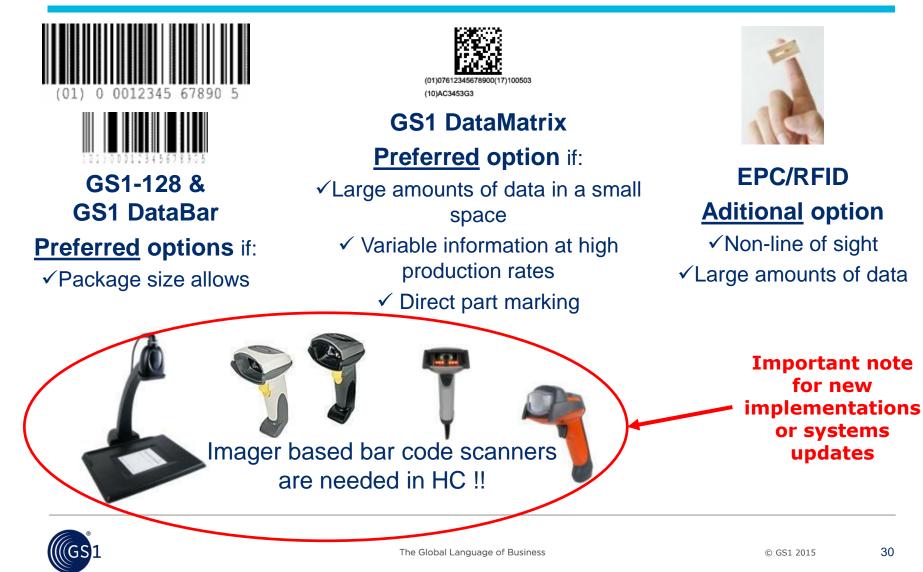
01	GTIN (Global Trade Item Number)
10	Batch / Lot
11	Production Date
17	Expiry Date
21	Serial Number

Note – Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI's is *not significant and should not be mandated*.



GS1 Data carriers for Healthcare...





GS1 System Standards





GS1 General Specifications – the ONE global standard for AIDC in Healthcare

 The core standards document of the "GS1 System"... describes how GS1 keys & data carriers should be used - Available online at: <u>http://www.gs1.org/docs/barcodes/GS1_Gener</u> <u>al_Specifications.pdf</u>

GS1 Healthcare GTIN Allocation Rules – GTIN assignment in Healthcare

A guide to GS1 ID Key assignment... the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at:

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

Many countries have already adopted GS1 Standards... and we anticipate many more!





Throughout the conference sessions there will be AIDC related presentations... such as:

Tuesday 12:30 – 12:55 – ONE barcode for traceability and product information – pilot report from UAE

Tuesday 14:00 – 15:30 – Ask the Experts: GS1 DataMatrix

Chuck Biss - Senior Director, AIDC Healthcare – GS1 Global Office

Tuesday 14:00 – 15:30 – Ask the Experts: Patient and caregiver identification

Christian Hay - Senior Consultant - GS1 Global Office

Wednesday 10:05 – 10:35 – UDI – experiences of implementation of the U.S. FDA UDI rule

Andrea Mitchell - Project Manager | Regulatory Affairs - Medtronid



For more information...





www.gs1.org/healthcare

www.gs1.org/healthcare/standards



For more information...



AIDC in Healthcare

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The Global Language of Business

The use of GSRN for Patient and Care provider identification

Christian Hay



Uniqueness of Patient ID – the challenge



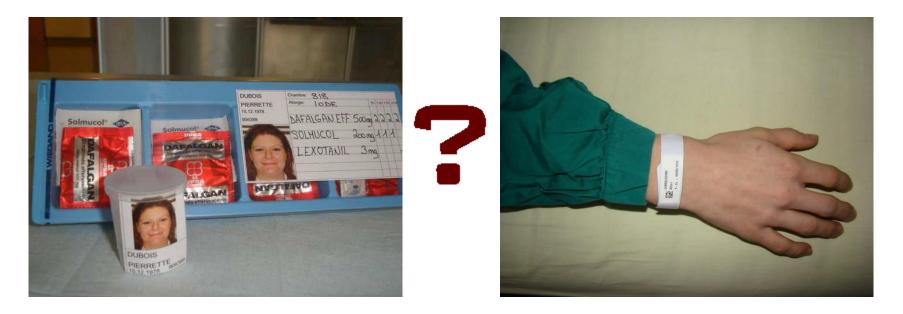




Positioning the problem



- Identification of subject of care is recognised priority and key to secure health care
- Which solution would be acceptable and efficient?





Efficiency by providing a homogeneous scanning environment



Homogeneous environment for scanning implies that one single system of standards is used





Homogeneous scanning environment









The Global Language of Business

GSRN – definition, structure and attribute



Definition GSRN (Global Service Relation Number)

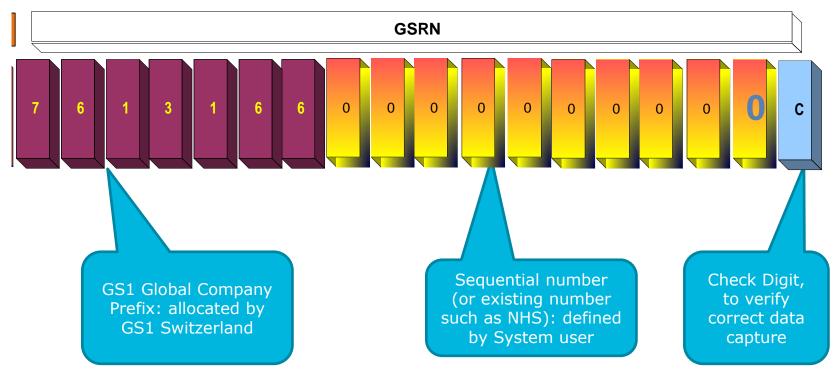


- Global Service Relation Number (GSRNs) can be used to identify the service provider and/or service recipient in any service relationship. A separate, unique number can be issued, normally by the organisation offering the service to identify the service provider and/or the service recipient, to identify any given service relationship. Once assigned, the GSRN becomes a unique and universal reference that can be used by all parties involved in the service relationship.
- A GSRN with either AI 8018 or AI 8017 are mutually exclusive, that is, a GSRN can only be assigned to a single role, recipient or provider, but not both.





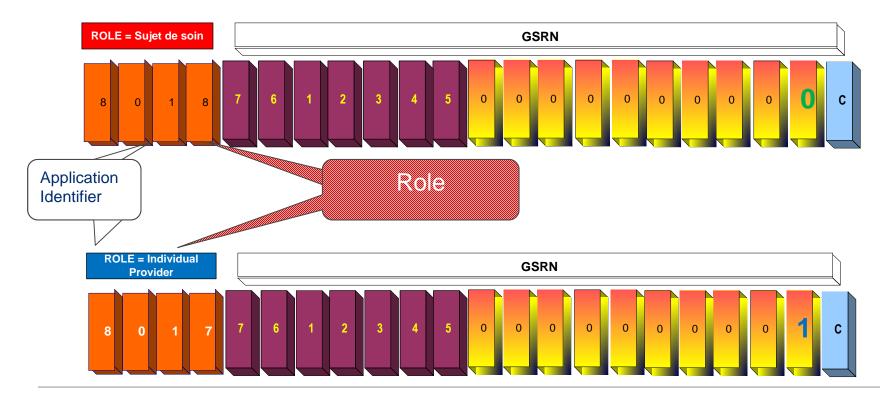
Format for both Subject of Care Identification and Individual Provider Identification is the « Global Service Relationship Number » (GSRN)







Distinguish provider from recipient of service

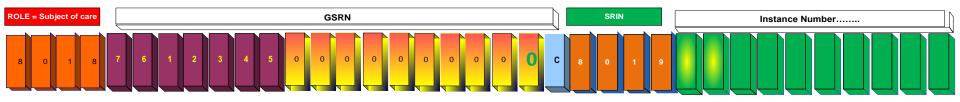




Application Identifier 8019



 The Service Relation Instance Number (SRIN) is an attribute to the GSRN which allows distinguishing different encounters during the same episode, or the reuse of the same GSRN in different episodes. SRIN is a 10 numeric digits variable length filed.



 For compliance with ISBT 128, the SRIN shall be used as a fixed length string with the first two digits (NN) reserved for the ISBT 128 location code (Table RT018); the selection of the remaining eight (8) digits is left to the discretion of the user and may be incremental.





CEN ISO TS 18530

- Technical Specification which provides guidance on actual and future users / implementers of "bedside scanning"
- Built on a series of use cases, which illustrate the benefits of using a global standardized identification of patients (in their relation with the care provider) and the healthcare professionals (in their relation with the provider they work with).

- CEN ISO TS 18530 does not replace or supersede GS1 General Specification.
- To be used as a kind of a good practice and high level implementation guide









Liaison with other Standard Organisations in Healthcare

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Managing Master Data Global Location Numbers Inaccurate or bad data adds risk and cost

Pete Alvarez, Senior Director Master Data Management







- Master Data Management & Data Quality
- The Global Data Synchronisation Network
- Global Location Numbers & the GLN Service





Every company has a database filled with master data about the products they make, sell, or buy

But when one company changes any bit of information in their database or add a new item, another database becomes outdated!





The Australian data crunch report puts a cost on the problem!





Potential savings for 5 scenarios studied

Potential cost of urgent deliveries due to undersupply





© GS1 2016

Source: https://www.gs1au.org/resources/publications/

\$8.75 million pa

\$6.98 million pa

Potential cost associated with independently

sourcing product weight and dimensions

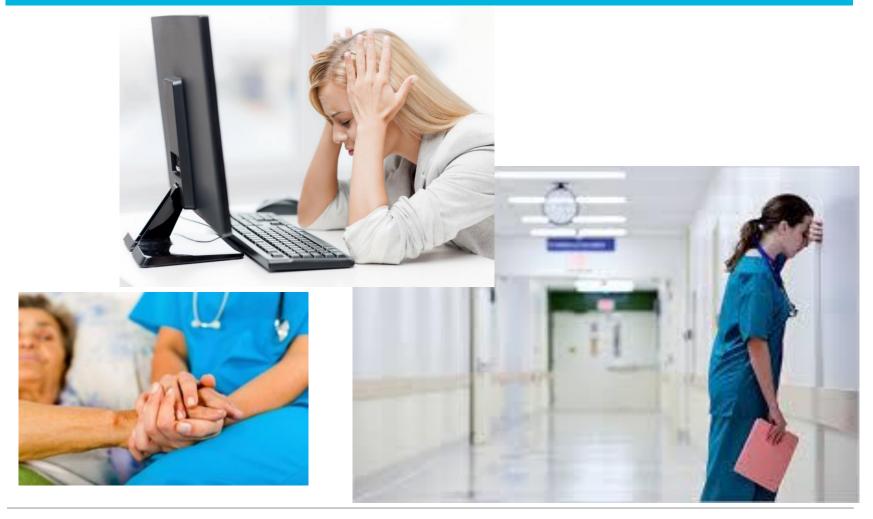
Potential lost revenue from unclaimed joint replacement prostheses



 Conservative potential savings from improved – data quality for all business processes met by the NPC data set

The most important impact: Patient safety and care providers







We need to understand the provider's data pain points...



...in order for them to <u>trust</u> & <u>use</u> the data





The challenge : for hospitals



Product catalogues - current situation:

- Ineffective methods of communicating information
 - Supplier A printed catalogue
 - 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)
- Varying levels of data quality

Hospitals need single and integrated source of "trusted data" on all products consumed



Managing Master Data How to improve?



Supplier = data source Needs single point-ofentry

 One database to load new item data and update data on existing items

Needs security

 Authorisation access by supply chain partners

Standards-based

- Standard identification keys
- Predefined (set of) product attributes

Hospital = data recipient Needs single point-oftruth

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

Standards-based

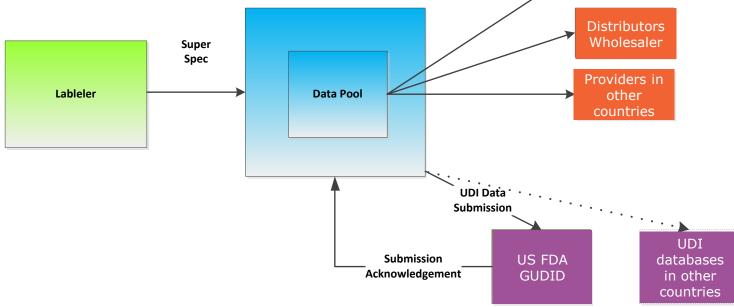
- Standard identification keys
- Consistently formatted information
- Complete information



Managing data at local level and global levels



- Find a standards based solution which can scale as the demand for data increases (i.e. GDSN and certified Data Pools)
- 2. Find a technology partner that can **connect you globally**
- 3. Define ALL regulatory and commercial attributes (Super In country Spec)





Master Data Management (MDM)





Data Governance



Roles and Responsibilities



Enterprise wide Data Management

Data Quality

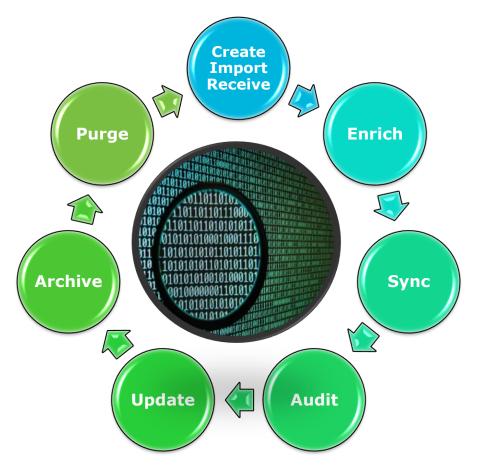
The quality of the data is reflection on the quality of the product



Information lifecycle management Key Concepts – Information Lifecycle Processes



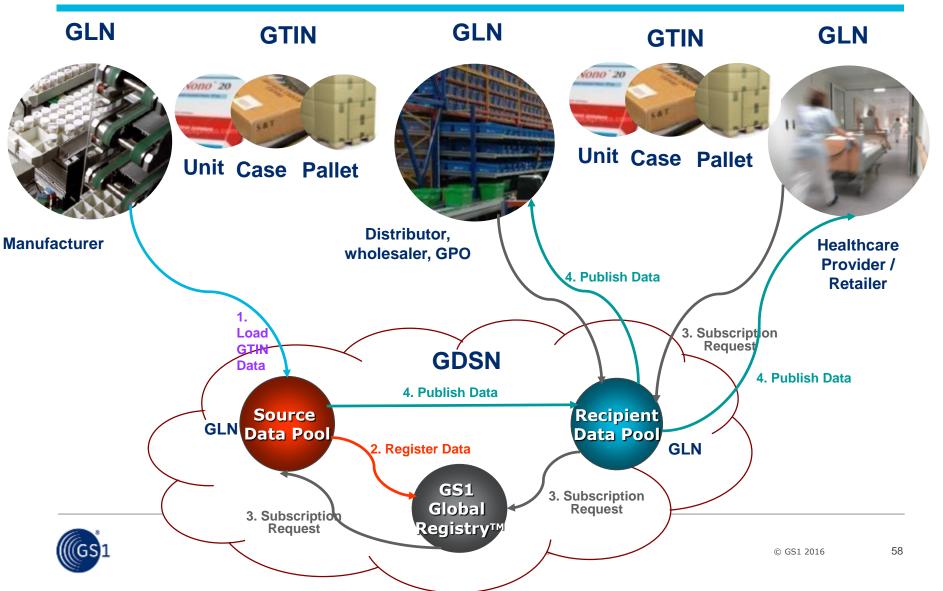
- Collect, Create, Receive & Capture
- 2. Enrich/Validate
 - Data Quality
- 3. Sync/Activate
 - Push to users
- 4. Audit/Evaluate
 - Routine Monitoring
- 5. Update/Maintain
 - Maintain, Protect & Preserve
- 6. Inactivate/Archive
 - Remove from active use
- 7. Purge
 - Delete from system



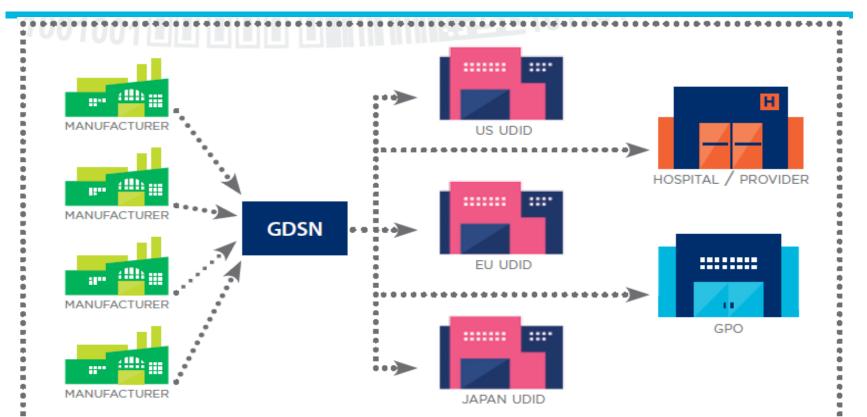


The Global Data Synchronisation Network (GDSN) in action





The right data for the right product to the right recipient



Manufacturers can register their product data in the GDSN and make it available to all of their customers worldwide, in secure and trusted environment. At the same time they can direct their Data Pool to register the appropriate device data in the GUDID, and any other UDI database anywhere in the world when they come online, via a single connection.



The Global Locations Number (GLN)



The problem with location identification



- SAINT JOHN'S QUEENS HOSPITAL
- 1100004570208
- ST JOHN'S QUEENS HOSPITAL
- 100084547
- SAINT JOHNS QUEENS HOSPITAL
- JAOE
- SAINT JOHN'S QUEEN HOSPITAL
- 50003000431
- SAINT JOHN'S QUEEN'S HOSPITAL
- CA2053
- ST. JOHN'S QUEENS HOSPITAL
- OM 12345

Many different names different location numbers for 1 hospital



The problem with location identification in healthcare



Manufacturor	Manufacturer	
Manufacturer SOUTHLAND TECHNOLOGY 3M	3M 800-327-5380	3M C/O EE
3M CO PHOTO PRODUCTS DIV	3M 600-327-3380	3M C/O EL
3M DIAGNOSTIC SYSTEMS INC	3M DENTAL 800-237-1650	3M C/O GC
3M ELECTRICAL SPECIALTIES DIV	3M ESPE DENTAL DIVISION 800-364-3577	3M C/O HC
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 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 & MG.CO.	3M C/O SA
3M MEDICAL/SURG	3M OCC. HEALTH AND ENVIOLE FETY DIV	3M C/O SC
3M PHARMACEUTICS AND MEDICAL S	3M OCC. HEALTH AND ENV. SPETY DIV.	3M C/O TH
3M-MEDICAL/SURGICAL	3M SARNS/CD	3M C/O TH
3M/ OCCUPATIONAL AND SAFETY DIV	3M SUDOCAL	3M C/O TH
3M - MINNESOTA MINING &	3// /N. =/ 800-423-4588	3M C/O TIV
co 🔦	NU ITEK	3M C/O W.
3M FEDERAL GOVERNMENT	THREE M/ ESPE	3M C/O W/
3M FEDERAL SYSTEMS DEPARTMEN	3M COMPANY NO. VAH∠ CORP. MINNES TA SCUNTIF	3M COMM
3M HEALTH CARE SYSTEMS	MINNEPOTA BOUNTIE	3M COMM
3M HEALTHCARE \$250 M AIM, M. CRDER	CUTPO & EALLIANCE 3M CUSTOMER SERV	3M COMP/
3M HEALTHCARE MINNIS THMINNING)	M. FALTHCARE	3M COMP/
3M MEDICAL - CR. DIT, ARD	3 UNITEK CORP	3M COMP/
3M MEDICAL PRODUCTS	3-M	3M COMP/
3M OCC. HEALTH AND ENV. SAFE 17 L VISION	3-M COMPANY	3M COMP/
3M OCCUPATIONAL AND CALETED DIV	3-M COMPANY-C/O O	3M COMP/
3M SAFETY DIVISION	3-M COMPANY-C/O OEM PRODUCTS	3M CONST
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

300 different names for the same supplier





Why use Global Location Numbers (GLN)

- A global standard for identification of legal entities and physical locations
- A GLN is an identification Key

Different locations in a hospital



- Vital for GS1 eCom messaging so that all parties and locations may be uniquely identified
- A pre-requisite for Global Data Synchronisation





Users need and expect a:

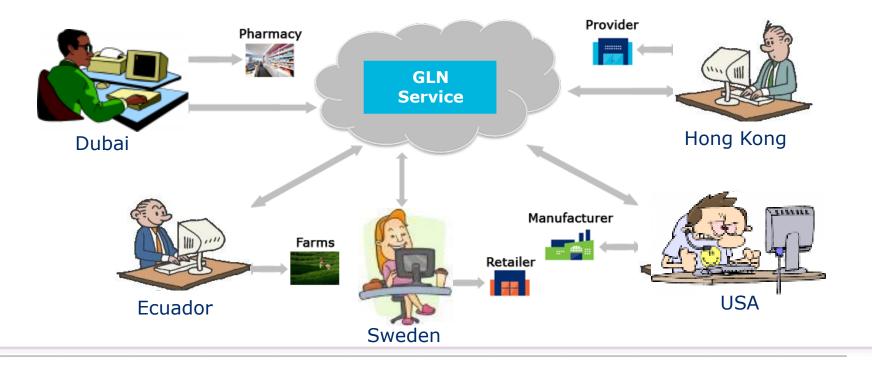
- simple and effective means of exchanging GLN and basic information with their trading partners "globally"
- single point of local access. They do not want to join multiple registries and pay multiple fees
- minimum set of attributes supported by all registries
- solution which can scale as the needs of the community grows



The GLN Service: Global exchange of GLN master data



Single point of access to GLN Master Data, globally, via the local GS1 Member Organisation





Data sessions This Week:



Tuesday 14:10 – 15:30 – Ask the Experts: Master Data Management

• Peter Alvarez, Senior Director Master Data Management

Wednesday 10:35 – 11:05 - GDSN implementation, UDI Databases and Product Data for Hospitals

- MJ Wylie, Global GDSN Deployment, Johnson & Johnson
- Nick Manzo, Global Senior Director of Industry Development, 1WorldSync

Wednesday 10:35 – 11:05 - Benefits of Quality Data and GS1 EDI for Healthcare

 Andrew Potter, Group Inventory Manager, Ramsay Health Care, Australia

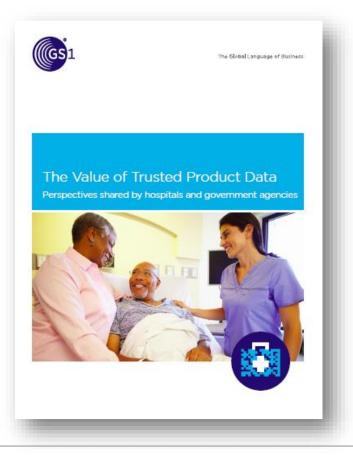


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Download the paper



http://www.gs1.org/healthcare/share-data





Contact Information





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For more information





www.gs1.org/gdsn

www.gs1.org/healthcare



EPCIS

Craig-Alan Repec, GS1 Global Office





The Global Language of Business

Event Based Traceability in Healthcare

Your 15-minute EPCIS primer...

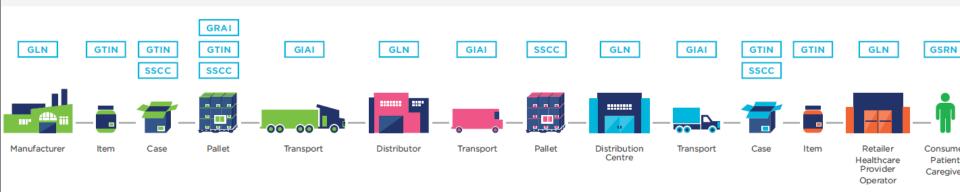
Craig Alan Repec, Senior Manager EPCglobal Technology, GS1 18 April 2016 in Dubai





Identify: GS1 Standards for Identification

GLN Global Location Number GTIN Global Trade Item Number SSCC Serial Shipping Container Code GRAI Global Returnable Asset Identifier GIAI Global Individual Asset Identifier GSRN Global Service Relation Number



Capture: GS1 Standards for Barcodes & EPC/RFID



EPCIS, a GS1 open standard . . .

- defines technical interfaces for capturing/sharing data
- defines a framework data model for event data
- helps create & share visibility data within/across enterprises
- enables services and solutions for supply chain visibility
- GS1 Keys identify the "what" & "where" of visibility events... ...encoded as data-carrier neutral EPCs ...even when used with GS1 barcodes (instead of RFID)
- Approved as **ISO/IEC 19987** in July 2015







WHAT objects are the subject of event? Individual objects (SGTIN) or groupings (GTIN + Lot/batch)

WHEN did this event take place? Date, time, time zone

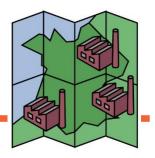
WHERE did this event take place? GLN of physical location & object's subsequent whereabouts

WHY did this event take place?

Business step, Disposition, Source/Destination info



EPCIS enables supply chain visibility



• Tracking

Where are the pharmaceuticals I shipped?

• Tracing

Where did this batch of pharmaceuticals come from?

- Chain of Custody (CoC) / Chain of Ownership (CoO) Which parties had custody of these pharmaceuticals?
- Recall

Where were meds produced on 14 April shipped to?

• Asset Management Where are all of the hospital's balloon pumps?



EPCIS implementations 2016 and beyond

- Food / Fresh Produce Packaging and Distribution
- Fish Packaging and Distribution
- Vehicle Visibility in Rail
- Digital Coupon Management in retail
- Asset management
- Apparel Stock-Taking & Cycle Counting
- **Pharmaceutical** chain-of-custody







DSCSA – 2015, 2017, 2023 Drug Supply Chain Security Act



Packaging level: Saleable units and homogeneous cases

- Data carrier: 2D DataMatrix
- Data elements: NTIN, expiry date, lot/batch, serial number

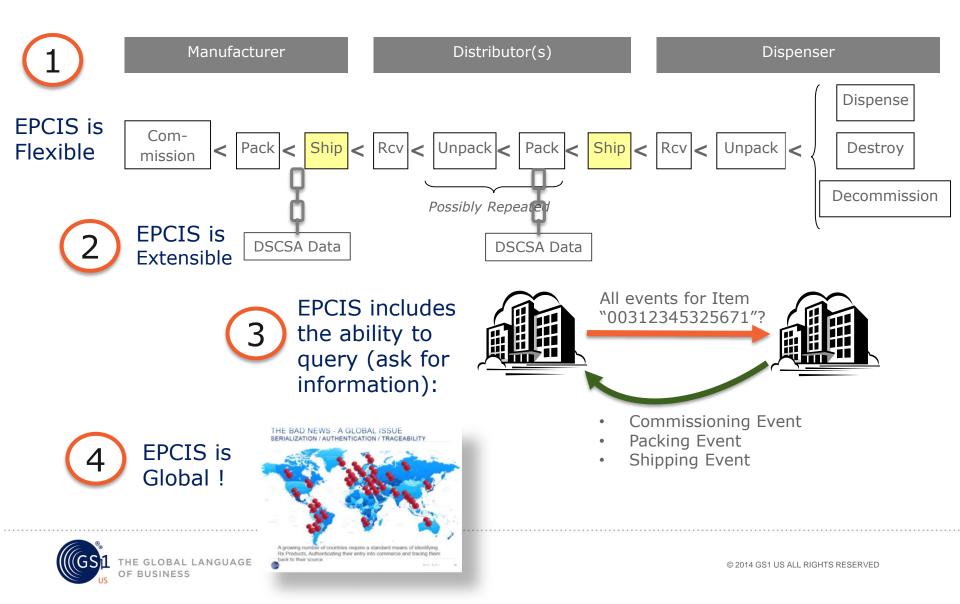
Deadlines

- 2015: Lot based (March 2016 for dispensers)
- 2017: Serialisation by manufacturers and repackagers
- 2023: Full traceability back to manufacturer or repackager

EPCIS is explicitly mentioned in a Nov 2014 US FDA draft guidance as a means for the interoperable exchange of pharmaceutical traceability data



EPCIS & DSCSA why EPCIS based traceability systems?



EPCIS Development activities – April 2016

- EPCIS/CBV enhancements (anticipated Q3 2016)
 - Support for event retraction / correction
 - Additional business vocabulary to satisfy Pharmaceutical regulations in US (FDA DSCSA) and Brazil (Anvisa)
 - Specification of Master Data attributes for EPCIS events
- GCP Length Table published and accessible online <u>http://www.gs1.org/gcp-length</u>
 - Machine-readable file to determine length of GS1 Company Prefix
 - Will simplify use of EPCIS in conjunction with pharmaceutical products that are serialized and barcoded with GS1 DataMatrix
- GS1 US Rx Guideline for DSCSA <u>www.GS1US.org/RxGuideline</u>
 - Application of EPCIS for serialized item-level traceability



Clearing up misconceptions on EPCIS

EPCIS <u>is</u> . . .

- a complex technical standard in GS1's "Share" layer
- an open ISO standard
- an enabler for commercial traceability solutions & services
- data-carrier-neutral, suited to GS1 DataMatrix barcodes

EPCIS is <u>not</u> . . .

- a product or service for sale by GS1
- an out-of the box solution
- a standalone answer to visibility issues
- GS1's portfolio is greater than the sum of individual parts
- Serialization and event-based traceability will fundamentally change how a supply chain works... EPCIS will support this





Craig Alan Repec

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EDI in Healthcare

An introduction

Tania Snioch, Director Healthcare, GS1 Global Office



GS1 EDI is part of the GS1 System of Standards

SSCC Serial Shipping Container Code

GIAI

SSCC

Pallet

GS1 DataBar

Item tracking

The globally unique identifiers of items, companies, locations, logistics units, assets, etc, are the foundation of the GS1 System that enables the different parts to work seamlessly together – we can link the physical flow with the information flow, transactional information to the pre-aligned master data and so on.

Enables physical items such as items and pallets to be marked with the unique identifiers and automatically capture through barcode and Radio Frequency (RFID) technology.

Defines how we share the information between stakeholder throughout the supply chain. The share level is further detailed in three areas: Master Data, Transactional Data and Event Data

Item master data

Identify: GS1 standards for identification

GTIN

SSCC

GS1-128

Share: GS1 standards for data exchange

SSCC

Capture: GS1 standards for barcodes and EPC/RFID

Location data

GTIN Global Trade Item Number

GIAI

ITF-14

Master data GLN Registry for Healthcare®, Global Data Synchronisation Network (GDSN) Transaction data GS1 EDI

GLN Global Location Number

GS1 barcodes

EAN/UPC

GTIN

GIAI Global Individual Asset Identifier

GLN

GS1 Composite

Barcode

Traceability

(Track and trace,

pedigree,

authentication)

IAI

GS1 QR Code

SSCC

Pallet

GLN

Distributo

GS1 DataMatrix

Interoperability

Order to cash

(Purchase order, despatch advice,

invoice)

GSRN Global Service Relation Number

GTIN

GLN

EPC UHF Gen 2

Patient Caregive

GTIN

SSCC

GS1 EPC/RFID

Visibility event data EPC Information Services (EPCIS)

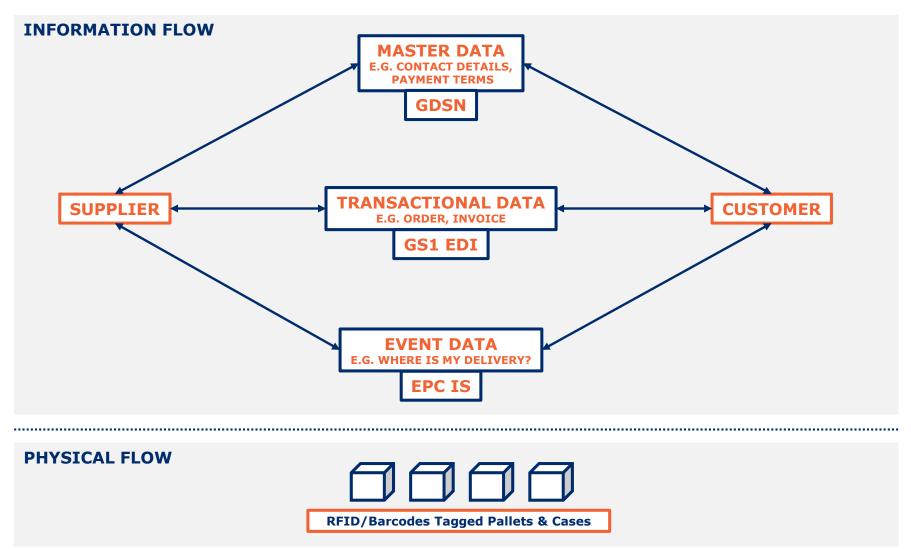
Product

recall/withdrawal

EPC HF Gen 2

GIAI

Information sharing





GS1 EDI Standards



GS1 Standards for Identification

Company & Location

• Global Location Number (GLN)

Product

- Global Trade Item Number (GTIN)
 Serialised Global Trade Item Number
- (SGTIN)

Logistics & Shipping

- Serial Shipping Container Code (SSCC)
- Global Shipment Identification
 Number (GSIN)
- Global Identification Number for Consignment (GINC)

Assets

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

Services & More

- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCN)





GS1 QR Code

EPC HF Gen 2

GS1 DataMatrix

GS1 EPC/RFID

Electronic

Code (EPC) RFID

Product

GS1 Composite

Barcode

BEIN BYANKER

EPC UHF Gen 2

Share

GS1 Standards for Data Exchange

Master Data

 Global Data Synchronisation Network (GDSN)

Transactional Data

• eCom (EDI): EANCOM, GS1 XML

Event Data

PC Information Services (EPCIS)

EANCOM

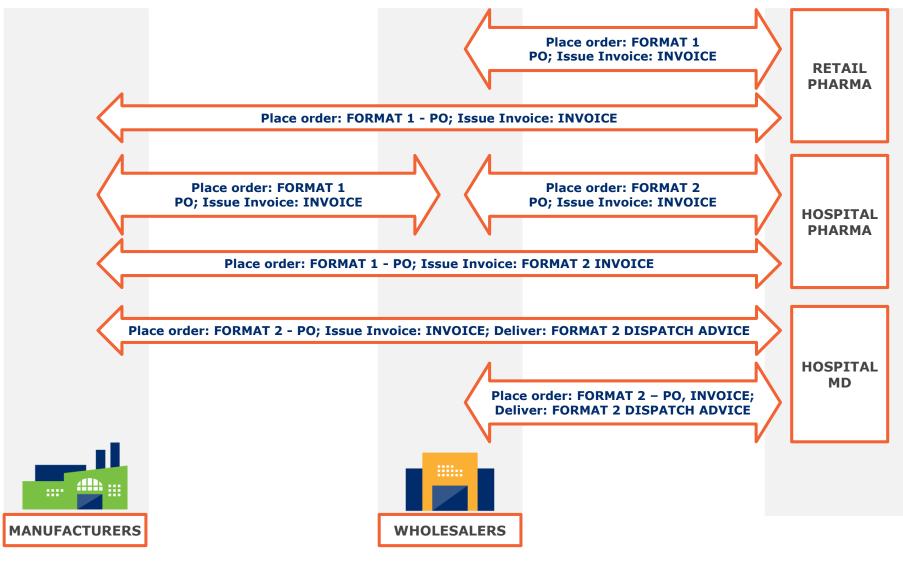
GS1 XML



The Global Language of

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EDI in Healthcare





EDI implementation drivers





Principles

Design principle for GS1 EDI

- Master Data alignment
 - All foundational information must be agreed and shared before exchanging EDI, such as contract details, delivery addresses, bank accounts
- Use of GS1 globally unique identifiers GS1 Keys
- Only coded information (machine readable) in EDI, exceptions:
 - Legal requirements
 - Text to be printed on paper, e.g. transport labels

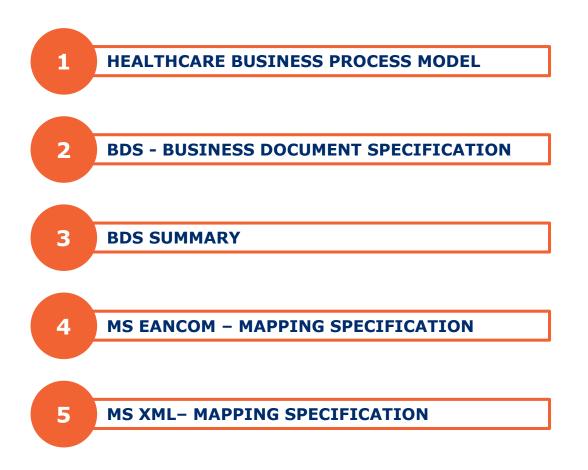
Global Guideline

- Global core processes and data
- Local guidelines adding legal requirements and specific processes

Business contents and technical information separated

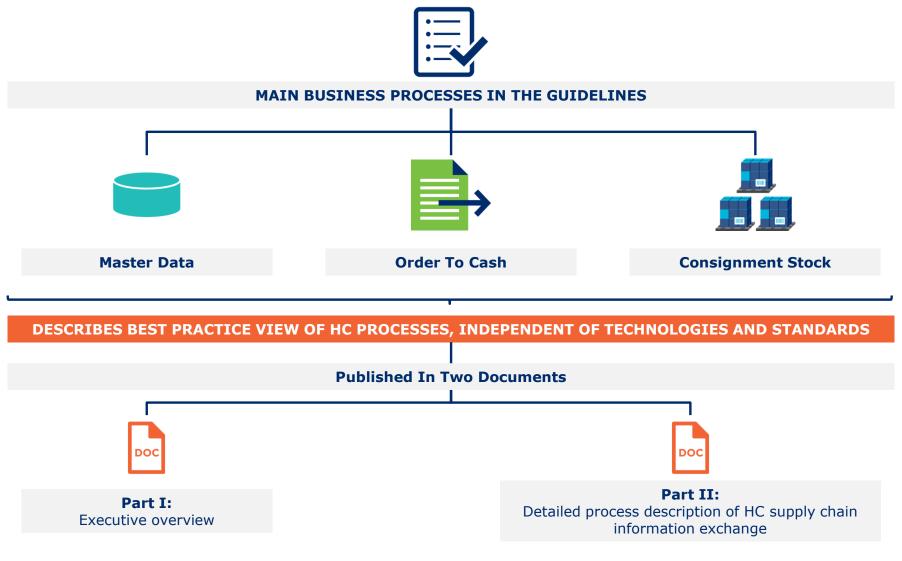


Global Guideline - Business contents and technical information separated

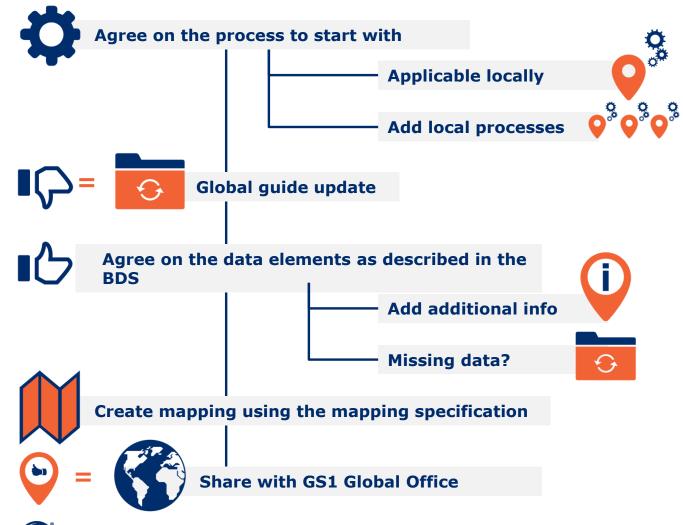




Healthcare Business Process Model



How to use the global guideline when creating local guidelines



Contact Information



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