GS1 Healthcare, the global perspective

Anouk Chavel, Global Marketing Lead, GS1 Global Office
Agenda of the session

1. GS1 Healthcare, the global perspective
   - Anouk Chavel

2. Automatic Identification Data Capture
   - Chuck Biss

3. Patient and care provider Identification
   - Christian Hay

4. Master Data Management and Global Location Numbers
   - Pete Alvarez

5. EPCIS
   - Craig-Alan Repec

6. Electronic Data Interchange (EDI)
   - Tania Snioch
GS1, most widely used standards
GS1 ensures end-to-end visibility in the supply chain

**Identify: GS1 standards for identification**

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

**Capture: GS1 standards for barcodes and EPC/RFDID**

**GS1 barcodes**
- EAN/UPC
- GS1-128
- ITF-14
- GS1 DataBar
- GS1 DataMatrix
- GS1 QR Code

**GS1 EPC/RFDID**
- GS1 Composite Barcode
- EPC HF Gen 2
- EPC UHF 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)

**Interoperability**

- Item master data
- Location data
- Item tracking
- Order to cash (Purchase order, despatch advice, invoice)
- Traceability (Track and trace, pedigree, authentication)
- Product recall/withdrawal
GS1 enables

**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
Our vision 2005

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

- patient safety
- supply chain security & efficiency
- traceability
- product data
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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www.gs1.org
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 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

Pete will cover next...
AIDC for Healthcare... the Vision

**EVERY** item has

**ONE** set of key identification data carried in

**ONE** data carrier

able to be scanned by **EVERYONE**

at every key process step...
Scope - All healthcare products...

Pharma / Vaccine / Nutritional

Medical devices

Retail

Non-retail
Scope – ID at all packaging levels...

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.

NOTE: * - Potentially a new definition that is needed...
Scope - Data & Data Carriers...

Data – a few examples:
- Global Trade Item Number (GTIN)
- Expiry Date
- Batch / Lot
- Serial Number

Data Carriers – a few examples:
- GS1-128 & GS1 DataBar
- GS1 DataMatrix
- EPC / RFID
Foundation of the GS1 System...

**GS1 Identification Keys**

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

1234567891234
GS1 Identification Keys...

Item identifier = **GTIN**
Global Trade Item Number

Logistics unit identifier = **SSCC**
Serial Shipping Container Code

Location identifier = **GLN**
Global Location Number

...and there are more ...

- Unique
- Non-significant
- International
- Secure
- Foundational
...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 **most commonly used at this time** (in various combinations) in Healthcare are:

<table>
<thead>
<tr>
<th>01</th>
<th>GTIN (Global Trade Item Number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Batch / Lot</td>
</tr>
<tr>
<td>11</td>
<td>Production Date</td>
</tr>
<tr>
<td>17</td>
<td>Expiry Date</td>
</tr>
<tr>
<td>21</td>
<td>Serial Number</td>
</tr>
</tbody>
</table>

**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...

**Preferred options** if:
- Package size allows

**GS1 DataMatrix Preferred option** if:
- Large amounts of data in a small space
- Variable information at high production rates
- Direct part marking

**EPC/RIFD Additional option**
- Non-line of sight
- Large amounts of data

Imager based bar code scanners are needed in HC!!

Important note for new implementations or systems updates
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: http://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

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 - Medtronic
For more information...

www.gs1.org/healthcare

www.gs1.org/healthcare/standards
For more information...

AIDC in Healthcare

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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.

- The right product, right dosage: GS1 GTIN
- The right location of care by the Healthcare provider: GS1 GLN
- The right patient, right caregiver: GS1 GSRN
  Right route of administration
Homogeneous scanning environment
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 of GSRN

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

© GS1 2016
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
For more information...

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
Topics

• Master Data Management & Data Quality
• The Global Data Synchronisation Network
• Global Location Numbers & the GLN Service
The master data problem

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 cost of manual checking of unit of measure: $8.8 million pa

Potential cost of manual PRC clarification by hospitals: $1.26 million pa

Potential savings from improved data quality: >$100 million per annum (pa)

Potential cost associated with independently sourcing product weight and dimensions: $6.98 million pa

Potential lost revenue from unclaimed joint replacement prostheses: $8.75 million pa

Potential cost of urgent deliveries due to undersupply: $4.37 million pa

Potential savings for 5 scenarios studied: $30 million pa

Conservative potential savings from improved data quality for all business processes met by the NPC data set: >$100 million pa

By conservative estimates, more than $100 million in potential savings can be achieved by addressing product data quality issues by making only minor adjustments to existing processes.

Source: https://www.gs1au.org/resources/publications/
The most important impact: Patient safety and care providers
We need to understand the provider’s data pain points...

...in order for them to trust & use 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-of-entry
• 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-of-truth
• 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

1. 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 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

1. Create, Import or Receive
   - 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

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

Manufacturer

Distributor, wholesaler, GPO

Healthcare Provider / Retailer

Source Data Pool

GS1 Global Registry™

Recipient Data Pool

GDSN
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 and different location numbers for 1 hospital
The problem with location identification in healthcare

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>SOUTHLAND TECHNOLOGY 3M</td>
<td>3M 800-327-0380</td>
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<td>3M CO FL</td>
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<td>3M DIAGNOSTIC SYSTEMS INC</td>
<td>3M DENTAL 800-237-1550</td>
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<td>3M HEALTH CARE 800-521-2818</td>
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<td>3M Mедсуро</td>
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<td>3M MEDICAL - CRITICAL CARE</td>
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<td>3M BIOLICAL</td>
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<td>3M MEDICAL - CRITICAL CARE</td>
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<td>3M HEARTLAGE</td>
<td>3M UNITEK CORP</td>
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300 different names for the same supplier could be any manufacturer
Why use Global Location Numbers (GLN)

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

Vital for GS1 eCom messaging so that all parties and locations may be uniquely identified

A pre-requisite for Global Data Synchronisation
Accessing GLN information globally

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

Dubai

Ecuador

Sweden

Hong Kong

USA
Data sessions

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
Download the paper

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

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www.gs1.org/gdsn

www.gs1.org/healthcare
EPCIS

Craig-Alan Repec, GS1 Global Office
Event Based Traceability in Healthcare

Your 15-minute EPCIS primer...

Craig Alan Repec, Senior Manager EPCglobal Technology, GS1
18 April 2016 in Dubai
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
Four dimensions of an EPCIS event

**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?

1. EPCIS is Flexible
   - Commissioning Event
   - Packing Event
   - Shipping Event
   - Receipt Event
   - Unpacking
   - Packing
   - Shipping
   - Receipt
   - Unpacking
   - Dispense
   - Destroy
   - Decommission

2. EPCIS is Extensible
   - DSCSA Data
   - Possibility of repetition

3. EPCIS includes the ability to query (ask for information):
   - All events for Item "00312345325671"?

4. EPCIS is Global!
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
  http://www.gs1.org/gcp-length
  • 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
  • Application of EPCIS for serialized item-level traceability
Clearing up misconceptions on EPCIS

**EPCIS is . . .**

- 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 not . . .**

- 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
For more information on EPCIS . . .

Craig Alan Repec
Senior Manager, EPCglobal Technology

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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

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.

Capture: GS1 standards for barcodes and EPC/RIFD

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.

Share: GS1 standards for data exchange

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

INFORMATION FLOW

SUPPLIER

MASTER DATA
E.G. CONTACT DETAILS, PAYMENT TERMS

GDSN

TRANSACTIONAL DATA
E.G. ORDER, INVOICE

GS1 EDI

EVENT DATA
E.G. WHERE IS MY DELIVERY?

EPC IS

CUSTOMER

PHYSICAL FLOW

RFID/Barcodes Tagged Pallets & Cases
GS1 EDI Standards

**Identify**
- **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)

**Capture**
- **GS1 Standards for Barcodes & EPC/RFID**
  - EAN/UPC
  - GS1-128
  - ITF-14
  - GS1 DataBar
  - GS1 DataMatrix
  - GS1 QR Code
  - GS1 Composite Barcode

**Share**
- **GS1 Standards for Data Exchange**
  - **Master Data**
    - Global Data Synchronisation Network (GDSN)
  - **Transactional Data**
    - eCom (EDI): EANCOM, GS1 XML
  - **Event Data**
    - EPC Information Services (EPCIS)

**EANCOM**

**GS1 XML**
EDI in Healthcare

- Place order: FORMAT 1 - PO; Issue Invoice: INVOICE

- Place order: FORMAT 1 - PO; Issue Invoice: INVOICE

- Place order: FORMAT 1 - PO; Issue Invoice: FORMAT 2 INVOICE

- Place order: FORMAT 2 - PO; Issue Invoice: INVOICE; Deliver: FORMAT 2 DISPATCH ADVICE

- Place order: FORMAT 2 - PO, INVOICE; Deliver: FORMAT 2 DISPATCH ADVICE
EDI implementation drivers

1. HELPING TO ENSURE QUALITY OF CARE
2. MEETING REGULATORY OR TRADING PARTNER REQUIREMENTS
3. FACILITATING PRODUCT TRACEABILITY
4. INCREASING BUSINESS EFFICIENCY, ACCURACY AND REDUCING COST
5. ENABLING NEW BUSINESS PROCESSES
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

1. HEALTHCARE BUSINESS PROCESS MODEL
2. BDS - BUSINESS DOCUMENT SPECIFICATION
3. BDS SUMMARY
4. MS EANCOM – MAPPING SPECIFICATION
5. MS XML – MAPPING SPECIFICATION
Healthcare Business Process Model

MAIN BUSINESS PROCESSES IN THE GUIDELINES

- Master Data
- Order To Cash
- Consignment Stock

DEscribes best practice view of HC processes, independent of technologies and standards

Published in two documents

Part I: Executive overview

Part II: Detailed process description of HC supply chain information exchange
How to use the global guideline when creating local guidelines

1. Agree on the process to start with
   - Applicable locally
   - Add local processes

2. Global guide update

3. Agree on the data elements as described in the BDS
   - Add additional info
   - Missing data?

4. Create mapping using the mapping specification

5. Share with GS1 Global Office
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