GS1 Lunch & Learn
Are you ready for UDI?

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GS1 Global Office

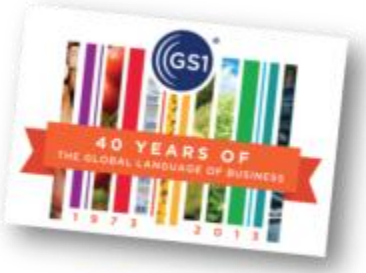
AHC-AHWP Joint Workshop

18 November 2014, Seoul - Korea

Disclaimer

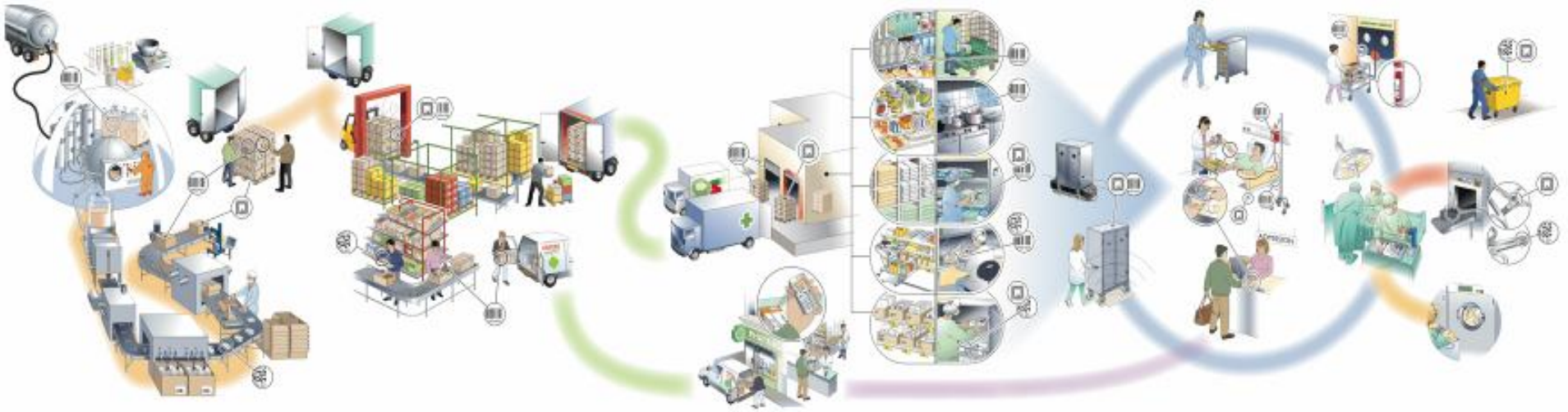
GS1 is an Issuing Agency for the US FDA Unique Device Identification Rule of September 2013. Neither GS1 nor its member organizations nor their staffs have real or apparent authority to speak for the FDA or grant exemptions. GS1 offers advisory services focused on the GS1 standard after a suppliers staff including its internal regulator experts have determined the correct path to compliance. GS1 is a voluntary organization and its members have and must continue to determine their own course of action. GS1 provides recommendations. GS1, GS1 member organizations and GS1 staff assume no liability for members actions taken upon its advice.

GS1 – an international standards organization



Not-for-profit
111 Member Organisations
Over one million user companies
(from SME to global companies)
Member driven
150 countries served; 20 different domains
2,500 people helping us
Over 6 billion transactions a day

GS1 Healthcare - a voluntary, global Healthcare User Group

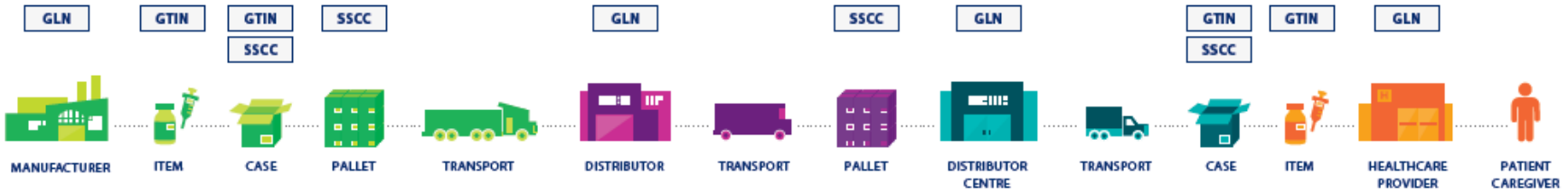


To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.

GS1 in Healthcare: global system of standards to ensure visibility

IDENTIFY: GS1 Standards for Identification

GLN Global Location Number **GTIN®** Global Trade Item Number **SSCC** Serial Shipping Container Code **EPC** Serialized Global Trade Item Number

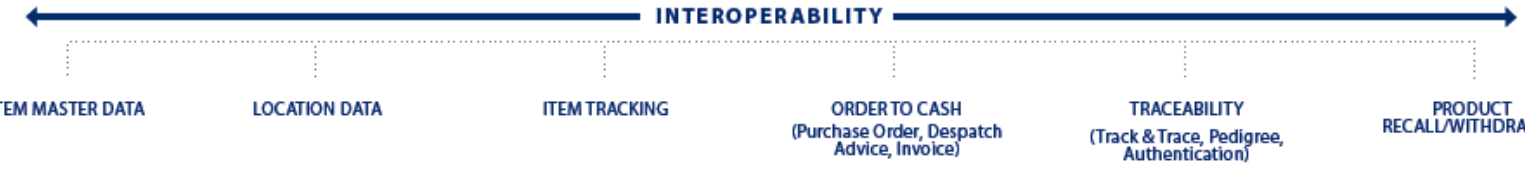


CAPTURE: GS1 Standards for Automatic Identification & Data Capture

GS1 BARCODES **GS1 EPC/RFID**

SHARE: GS1 Standards for Automated Data Exchange

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** eCom (EDI) **EVENT DATA** EPC Information Services (EPCIS)



UDI… WHAT? WHERE? WHEN?

- UDI: purpose
- UDI: scope
- UDI: global developments

UDI … LABELLING

- What are the U.S. FDA UDI labelling requirements ?
- What is the GS1 AIDC translation of UDI?

UDI… DATABASE

- What are the U.S. FDA GUDID requirements ?
- How do the GS1 GDSN support the implementation the UDI database?

KEY CHALLENGES

For the industry

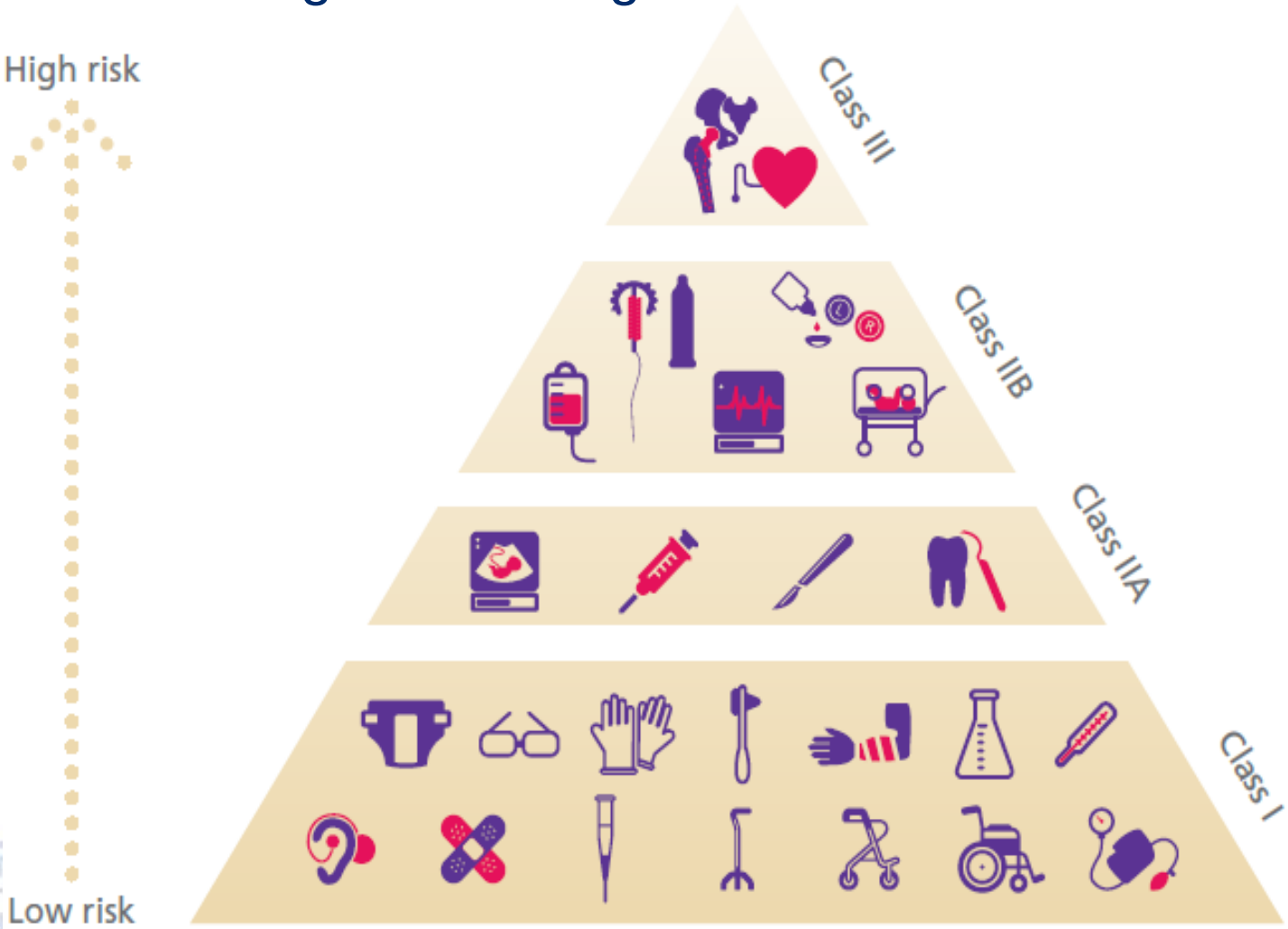
- Labelling
- Database elements and maintenance

UDI – purpose

A common, **worldwide system for product identification** should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.

UDI - scope

Varies from regulator to regulator – follow GHTF definition?

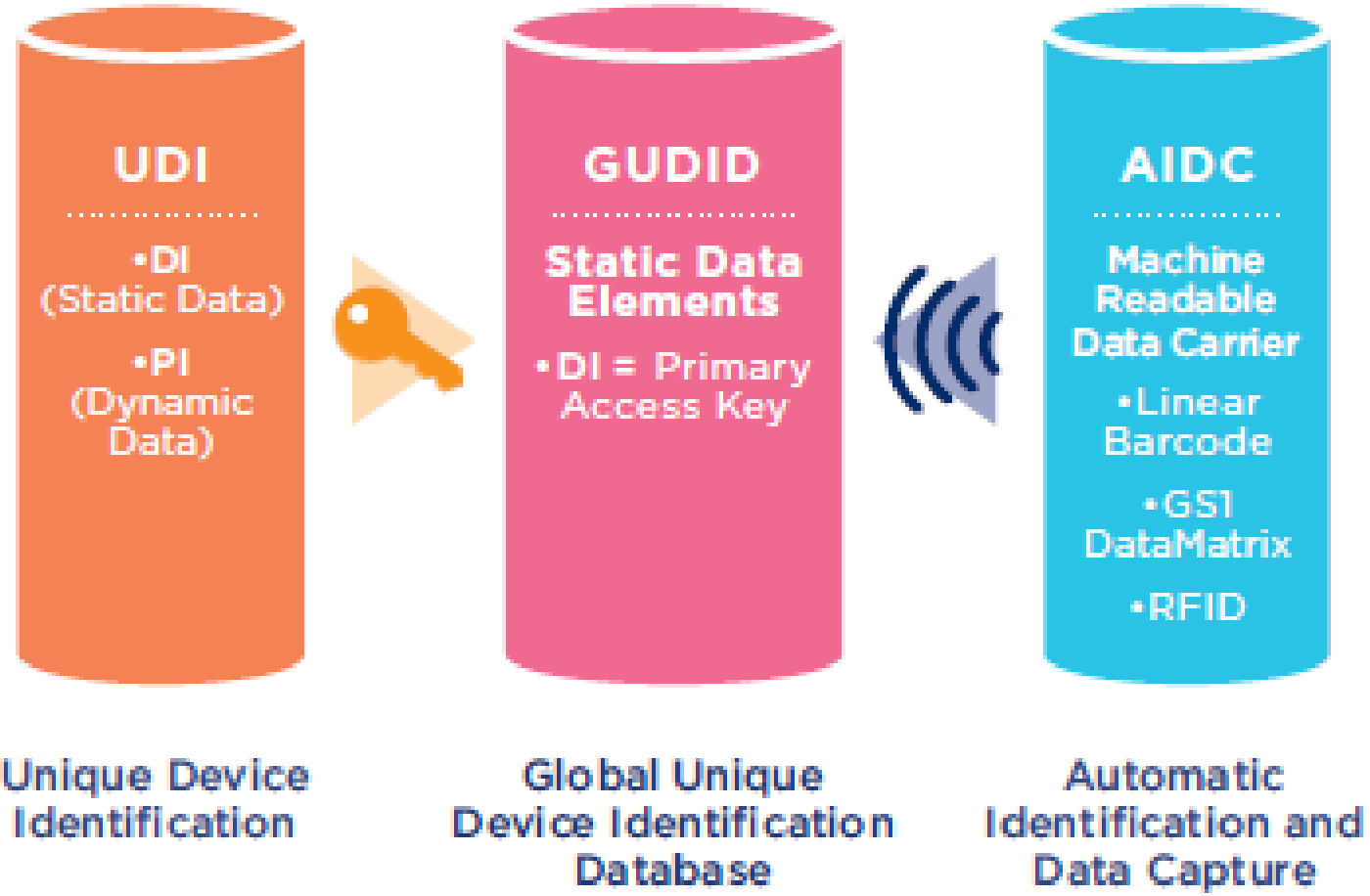


SOURCE: MedTech Europe,2013

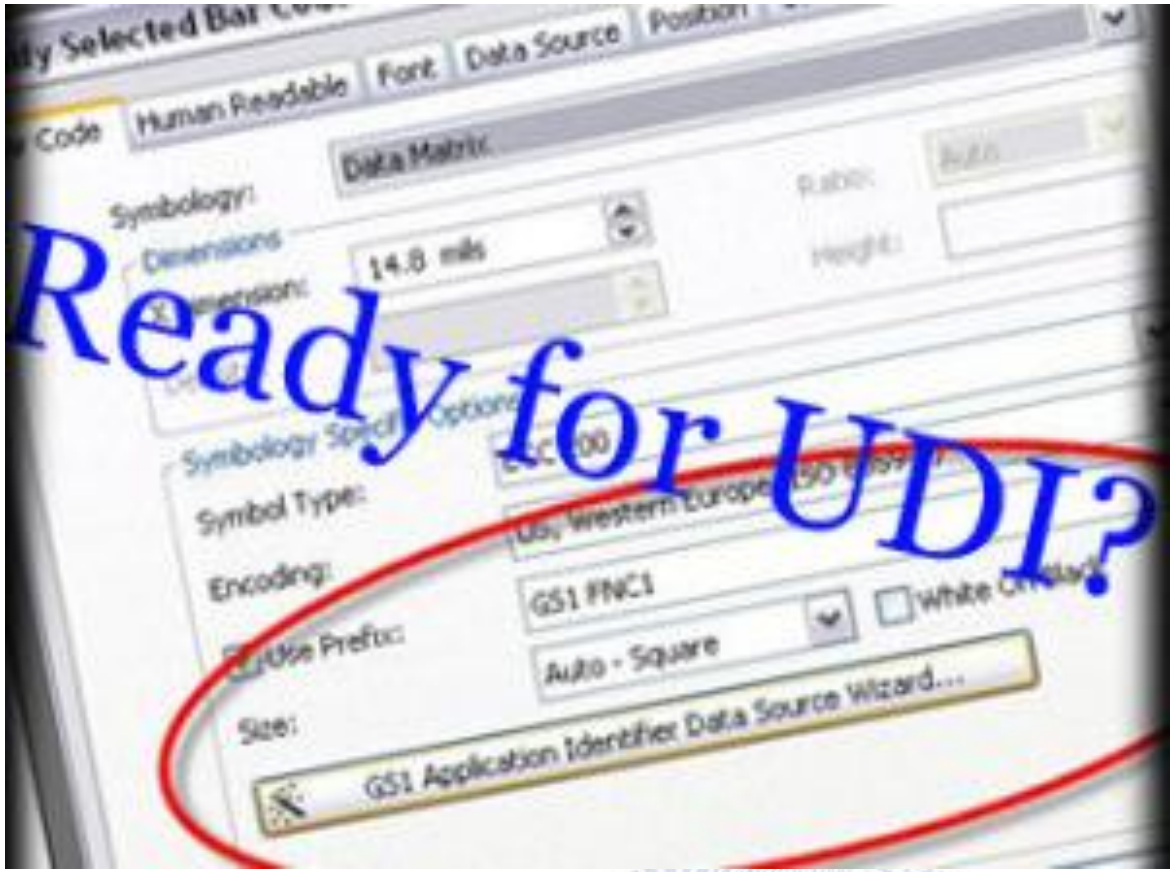
Establishing a UDI System

1. Assign a globally unique standardized identifier to devices
2. Place UDI on the label in both plain text (HRI) and in an appropriate form of Automatic Identification and Data Capture (AIDC)
3. Directly mark (DPM) those devices which are intended to be reused or reprocessed
4. Submit data related to product to US FDA's Global UDI Database (GUDID)
5. IMPLEMENTATION

UDI system at a glance



DI = Device Identifier
PI = Production Identifiers (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)


Ready for UDI?
Human Readable
Font
Data Source
Position
Code
Data Matrix
Symbology:
Dimensions
14.8 mils
Symbol Type:
Encoding:
GS1 FNC1
Auto - Square
Size:
GS1 Application Identifier Data Source Wizard...

“UDI” implementation in Turkey

Requirements as applicable:

TITUBB

- Implementation since a few years.
- All medical devices which are reimbursed are identified and marked. Approximately 2.5 million approved medical devices in the Turkish database.
- 91.8% identified with GS1 GTIN (Global Trade Item Number).

Open point(s)/upcoming dev.:

- MoH is working on a new project called UTS (Product tracking system) which will replace current system TITUBB.
- The main aim is to track products from manufacturing facility until end customer.
- Since September 2014, workshops with the industry to collect and give feedback to build the new system.
- New system is planned to be go-live on June 2017.

NHS Procurement

"WE WILL MANDATE THROUGH CONTRACTS THE USE OF GS1 CODING IN THE NHS"

NEHTA supporting the move towards UDI

- NEHTA Supply Chain Programme supporting implementation of the 3 UDI parts:
  - the identifier : using GTIN and relevant AIs (expiry date, serial number, batch/lot number)
  - the data carrier : recommanding to be in line the GS1 AIDC Healthcare Implementation guide
  - the UDI database : NETHA is working with GS1 Australia to ensure that the NPC is aligned with all UDI requirements
- **Ready in the market to implement UDI**

ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

- The first regulation requiring **traceability** for medical devices – with short timelines!

- *February 2015*: defibrillators/cardioverters, electric stimulators for cochlear hearing, intraocular lenses, cardiac pacemaker, breast internal prosthesis;
- *August 2015*: vascular coronary endoprosthesis (stent), hip prosthesis, and column prosthesis.

- GS1 standards required: GTIN plus AI's, GLN

The need to align on a global UDI framework

- It is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system

- This would ensure :
  - highest levels of patient safety beyond borders
  - harmonized identification systems for medical devices globally
  - allow for consistency in UDID across countries

GS1 Standards help save €1.1 million at NHS Leeds Teaching Hospitals (UK)

NHS Leeds Teaching Hospital – a 2,500-bed university hospital in the UK - Europe's largest university hospital

Issue(s)

- Increased pressure to improve patient safety and save costs in hospitals
- Suboptimal management of inventory of medical devices at the hospital's Orthopaedic Centre
- High stock levels and system integrity problems arising from consignment stock and vendor-managed inventory

Solution

- Implementation of an inventory control system through GHX
- Implementation of GS1 Standards, including GTIN, GS1 BarCodes and GDSN

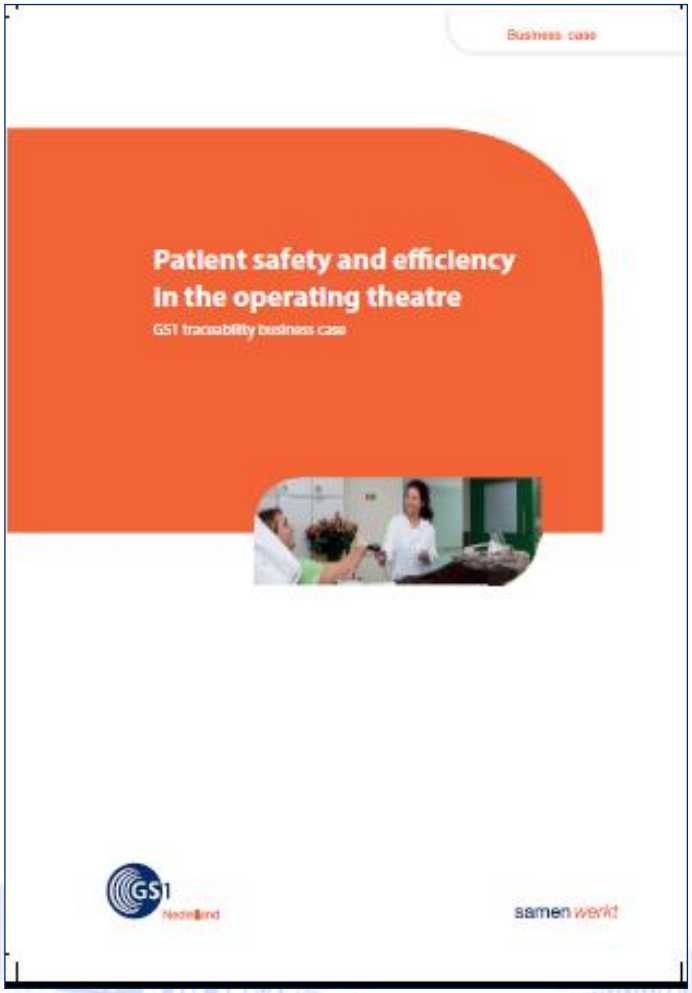
Results

Savings through consignment stock reduction: €600k
Savings through elimination of excess stock: €500k

- Reduced consignment stock, which reduces process and write-off costs for the supplier and the hospital
- Reduced obsolescence through stock visibility, stock rotation and stock levels that ensure usage within expiry
- Reduced emergencies thanks to improvements in forward demand/stock planning
- Reduced cost of carriage as stock delivered on efficient lead times and using scheduled deliveries

Business case in Netherlands

- Reduced inventory levels
- Reduced obsolete stock
- Simpler, faster ordering, delivery and billing process
- Accelerate recall procedures
- Effective use of consignment goods
- Costs captured per patient
- Fewer errors and manual actions



www.gs1.nl/samenzorgen/traceerbaarheid.html

GS1 endorsed by 60 stakeholders

KEY CHALLENGES

For the industry

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UDI… WHAT? WHERE? WHEN?

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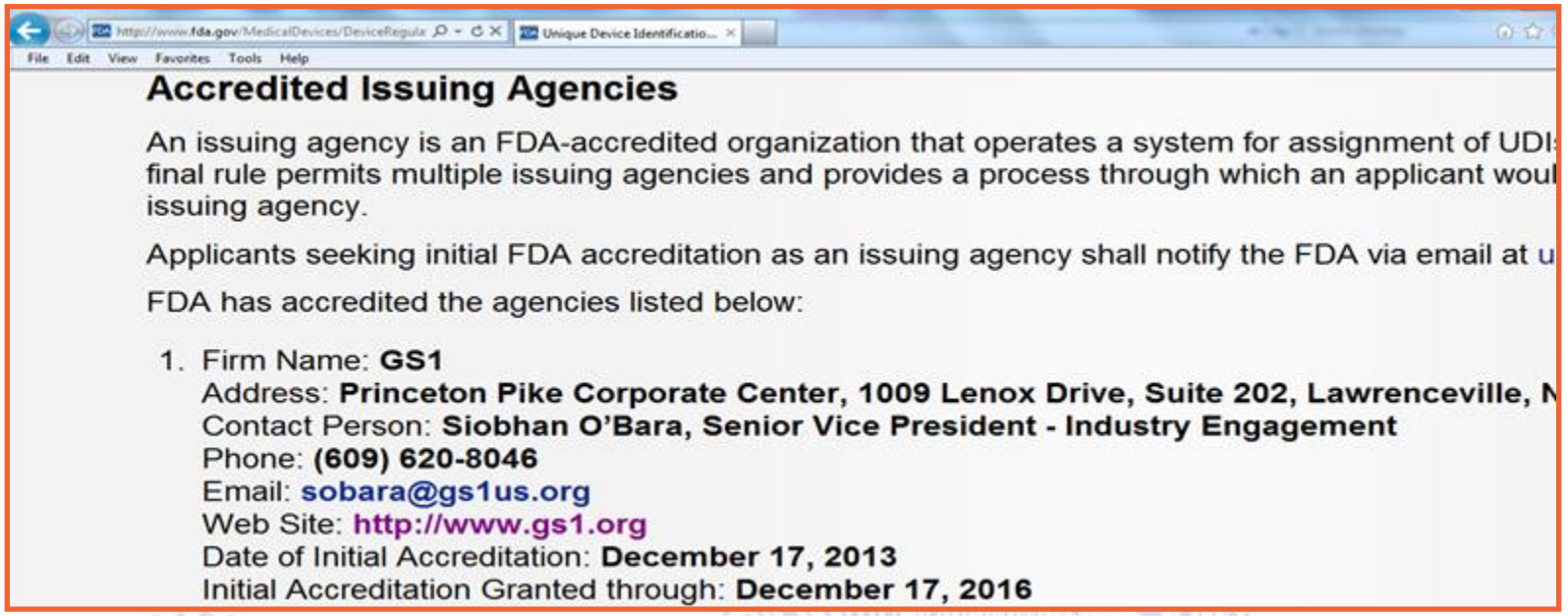
- UDI: scope
- UDI: global develoments

Long expected …

The final UDI rule of the US FDA of September 2013

GS1 was accredited as first issuing agency by the FDA



Compliance Dates

Implementation (compliance) timeframes – all September 24:

- 2014: class III and devices licensed under PHS Act
- 2015: class II/I implants and life-supporting/sustaining
- 2016: rest of class II
- 2018: rest of class I

For Direct Marking:

- Compliance dates are extended by 2 years
- NOT class II/I implants & life-supporting/sustaining: still in 2015

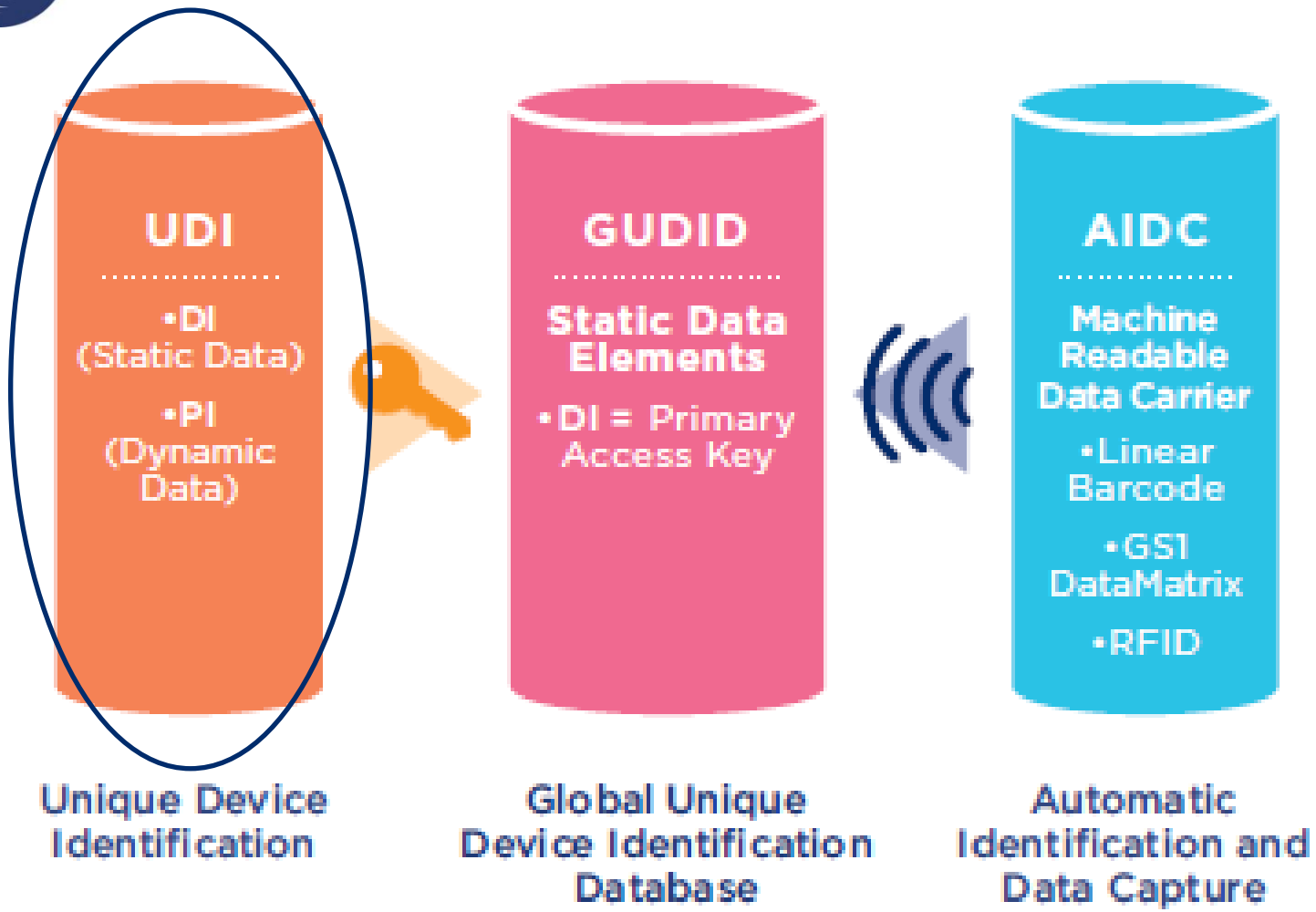
The US FDA UDI Rule

In general:

- **The label of EVERY medical device (including all IVDs) must have a UDI.**
- **EVERY device package** (contains a fixed quantity of a version or model) **must have a UDI.**
- Any other approach is an exception to or alternative from these requirements.

** Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...*

UDI system at a glance



DI = Device Identifier
PI = Production Identifiers (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

1. Assignment of identifier

- Assign Device Identifiers (DIs) to all devices
- One DI can only identify a single model or version
- A DI is forever – it can not be reused
- In principle follow the assignment rules of issuing agency – FDA defined a few rules when a new DI needs to be assigned:
  - For new version or model
  - New device package
  - Re-label of device

http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare

UDI number

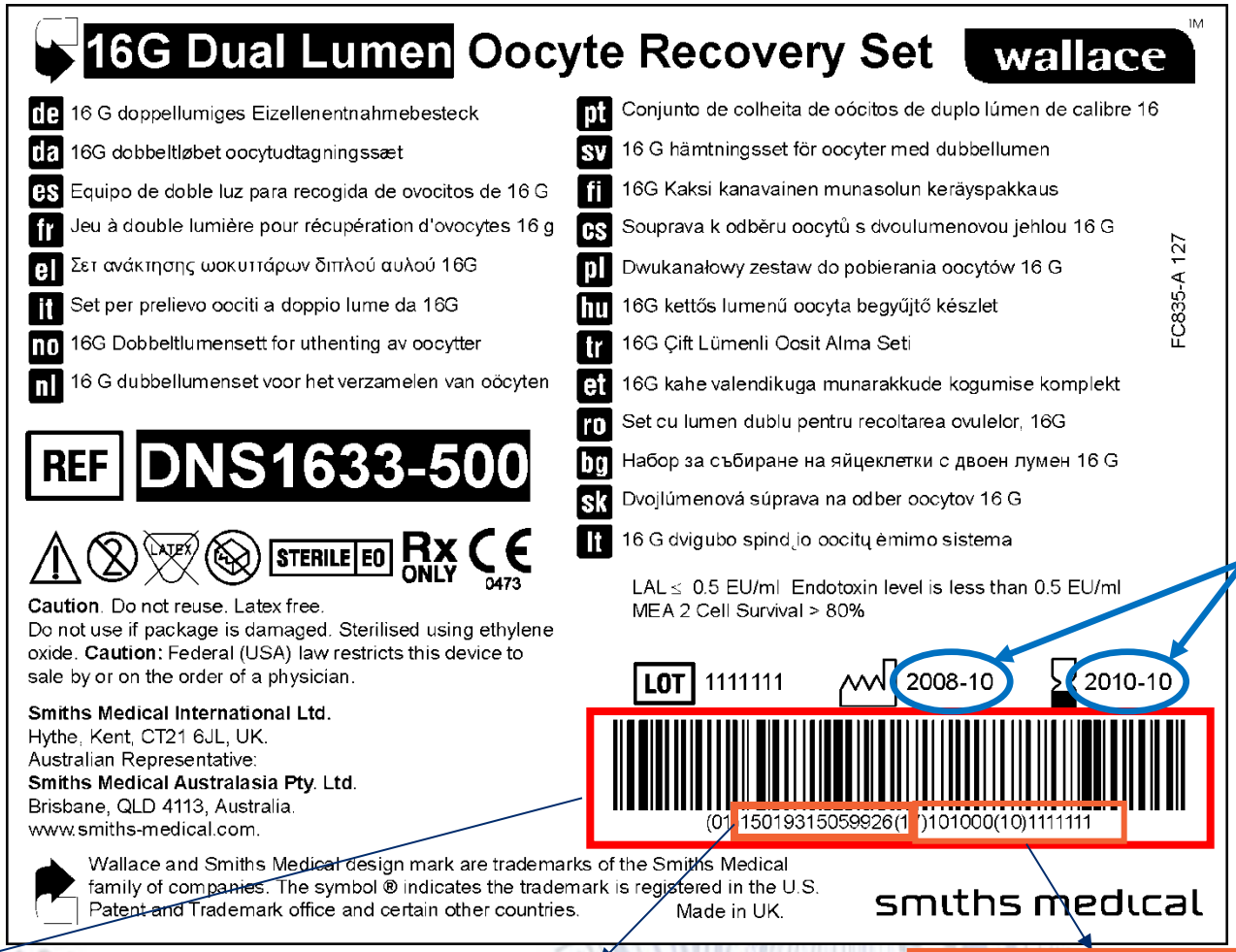
- Develop UDI number based on ISO 15459
-
- US FDA has accredited issuing agencies: GS1, HIBCC, ICCBBA
- Created and maintained by the manufacturer
- Device Identifier (DI) *Static* : manufacturer, make, model, catalogue number
- Production Identifier (PI) *Dynamic* : serial number, lot number, expiration/manufacturing date
- Phase out national numbering system (NDC/NHRIC)

UDI in the GS1 system of standards

…UDI in GS1 identification terms…

UDI Unique Device Identification	→	**GS1 Standards** Product Identification
DI Device Identifier (DI)	→	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (if applicable)	→	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.		
DI + PI = UDI	→	**GTIN or GTIN + AI(s) = UDI**

UDI example - #1



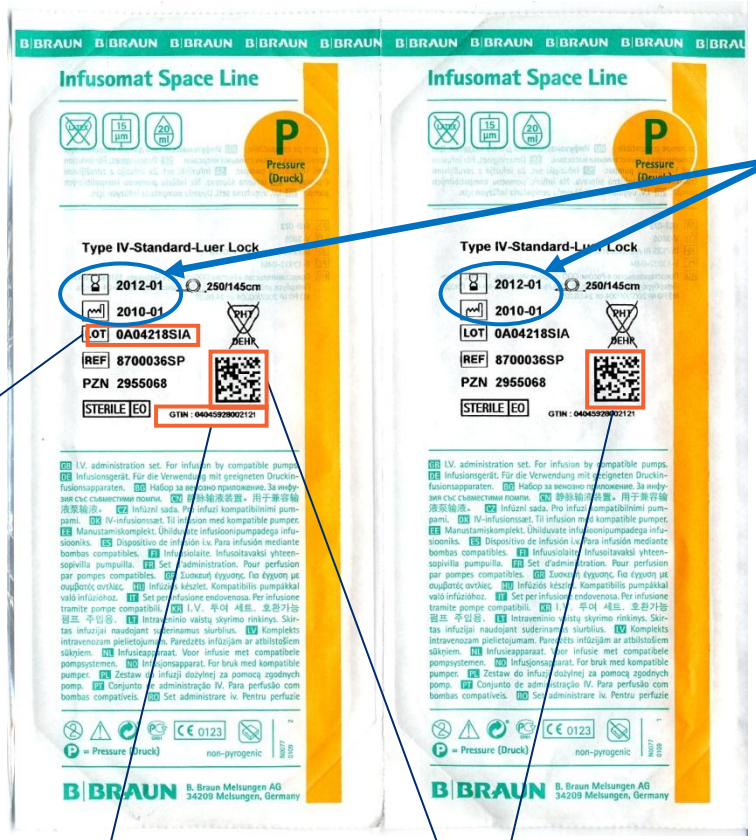
Note: These dates do not meet the US FDA UDI required ISO 8601 date format of YYYY-MM-DD

UDI Bar Code symbol

Device Identifier (DI)
GS1 GTIN

Production Identifier (PI)
GS1 Application Identifiers

UDI example - #2



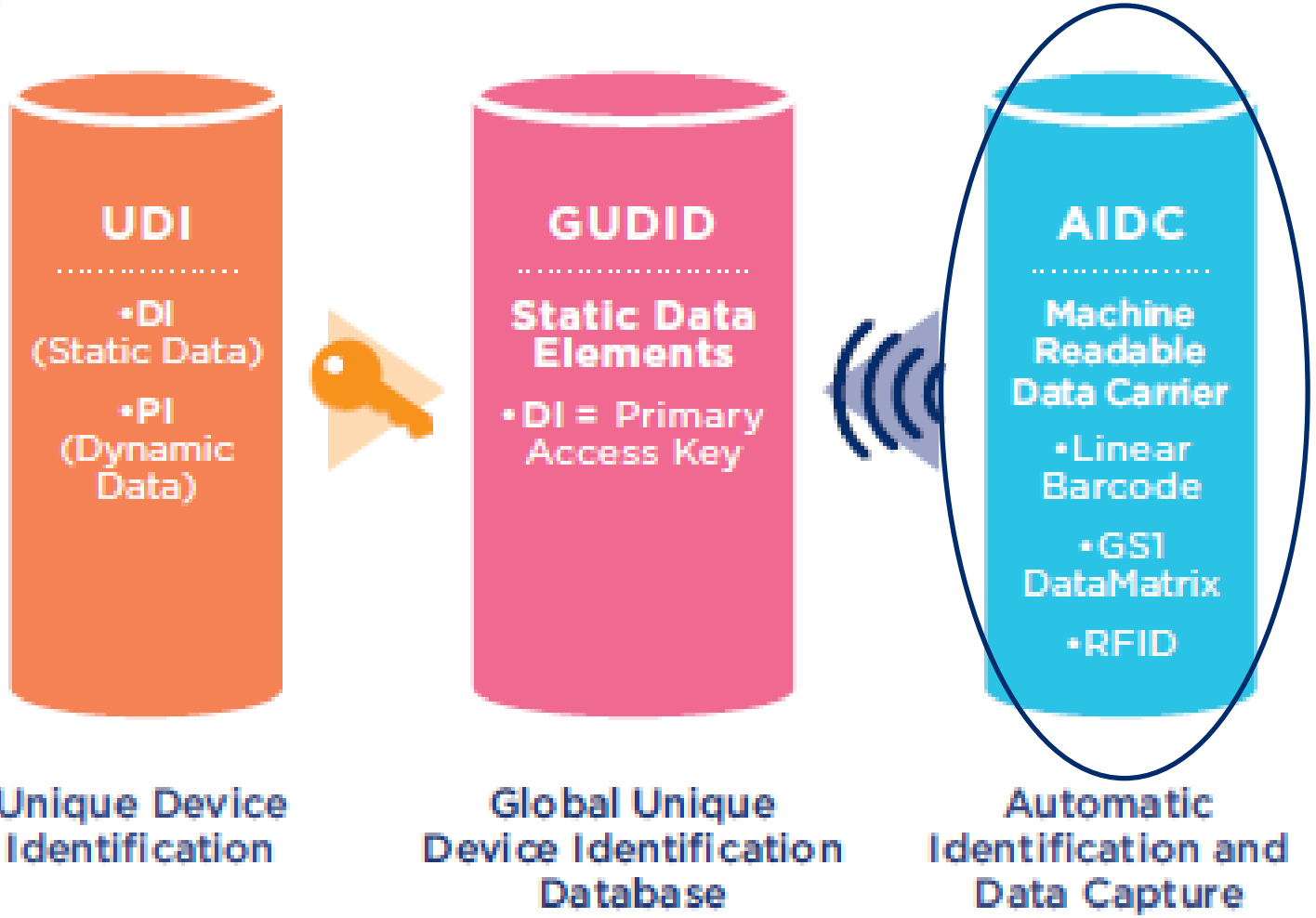
Note: These dates do not meet the US FDA UDI required ISO 8601 date format of YYYY-MM-DD

Production Identifier (PI)
GS1 Application Identifiers

Device Identifier (DI)
GS1 GTIN

UDI Bar Code symbol

UDI system at a glance



DI = Device Identifier
PI = Production Identifiers (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

2. Place UDI on label

- UDI must be applied in human readable information AND encoded in AIDC
- FDA did not prescribe the data carrier – must follow the rules of the issuing agency
- Consider capabilities of your trading partners and other regulations
- Bar code symbols should allow ready access for scanning when the product is stored or stocked on shelves
- For stand-alone software – UDI must be displayed also e.g. on label or screen.

Different packaging levels = different DIs (GTINs)

NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

Direct Marking Exceptions

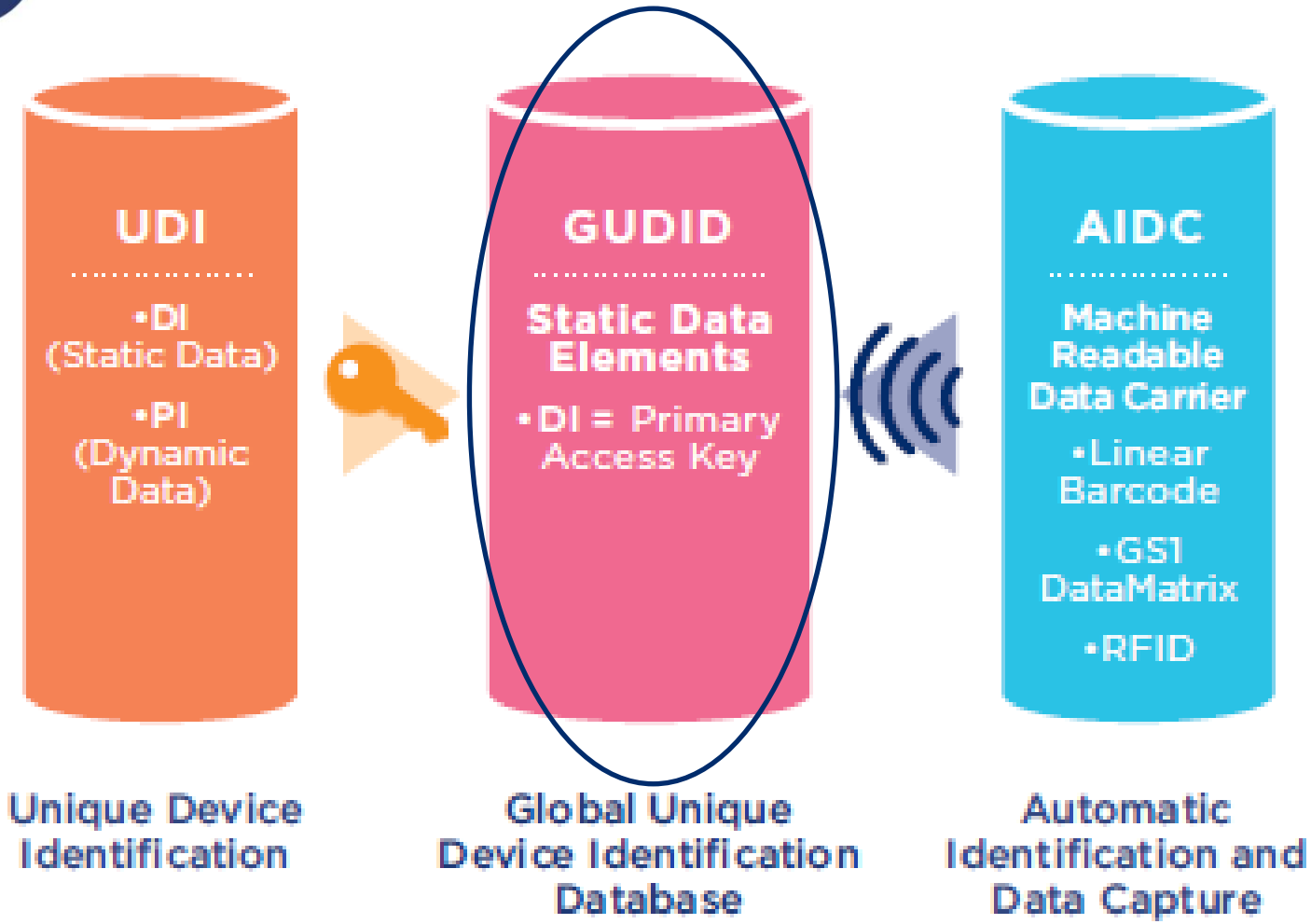
- Direct Marking (DM) for device intended to be used more than once and reprocessed before use
  - May be identical or different from label UDI
  - Either or both plain text and/or AIDC

Not necessary if

1. it would interfere with the safety or effectiveness of the device;
2. not technologically feasible;
3. device is single-use device
4. device has been previously marked

Exception needs to be noted in design history file

UDI system at a glance



DI = Device Identifier
PI = Production Identifiers (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

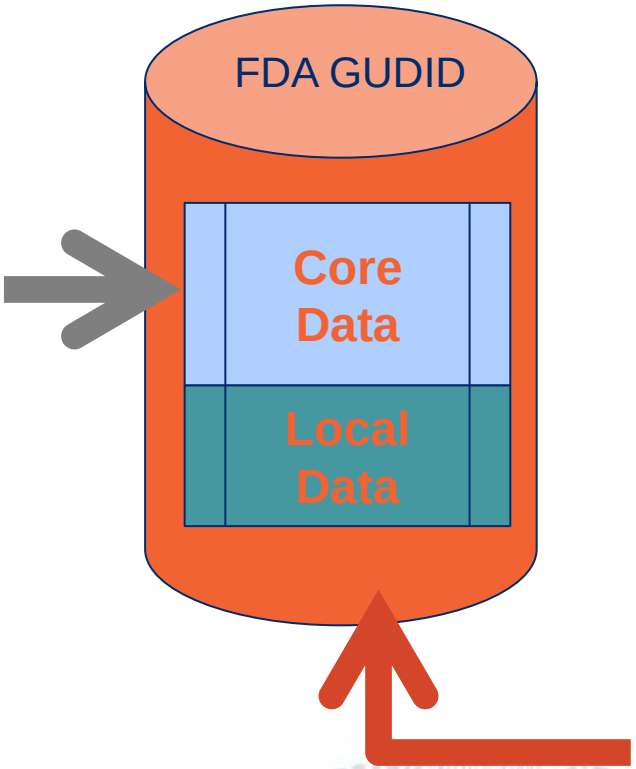
3. Product data submission

- So far the most challenging part for manufacturer
- Needs identification of location, organisation, maintenance, validation of data ACROSS an organisation
- Very often data are not available in electronic format
- All data need to be submitted to FDA's Electronic Submission Gateway (ESG)
- GUDID holds only STATIC data – so the DI plus attributes
- Details at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

UDI Databases:
Global Core Data + Local Data

- Packaging Hierarchy, per pack. level
  - DI / Unit of Measure / Quantity
- Unit of Use DI
- Manufacturer Name, Address, Contact info
- Authorized Representatives (list of countries)
- Nomenclature + Term (e.g. GMDN code)
- Brand Name
- Device Model or Version
- Reference Number (REF No./catalog no.)
- Controlled by (e.g. exp. date, lot no., serial no)
- Clinical Size (Size/Volume/Length/Gauge…)
- Special Storage Conditions
- Special Handling Conditions
- Labeled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use + Method
- Restricted number of reuses
- License / Marketing Authorization
- URL for additional information
- Critical warnings / contraindications as labeled
  - labeled as containing Latex
  - labeled as containing DEHP

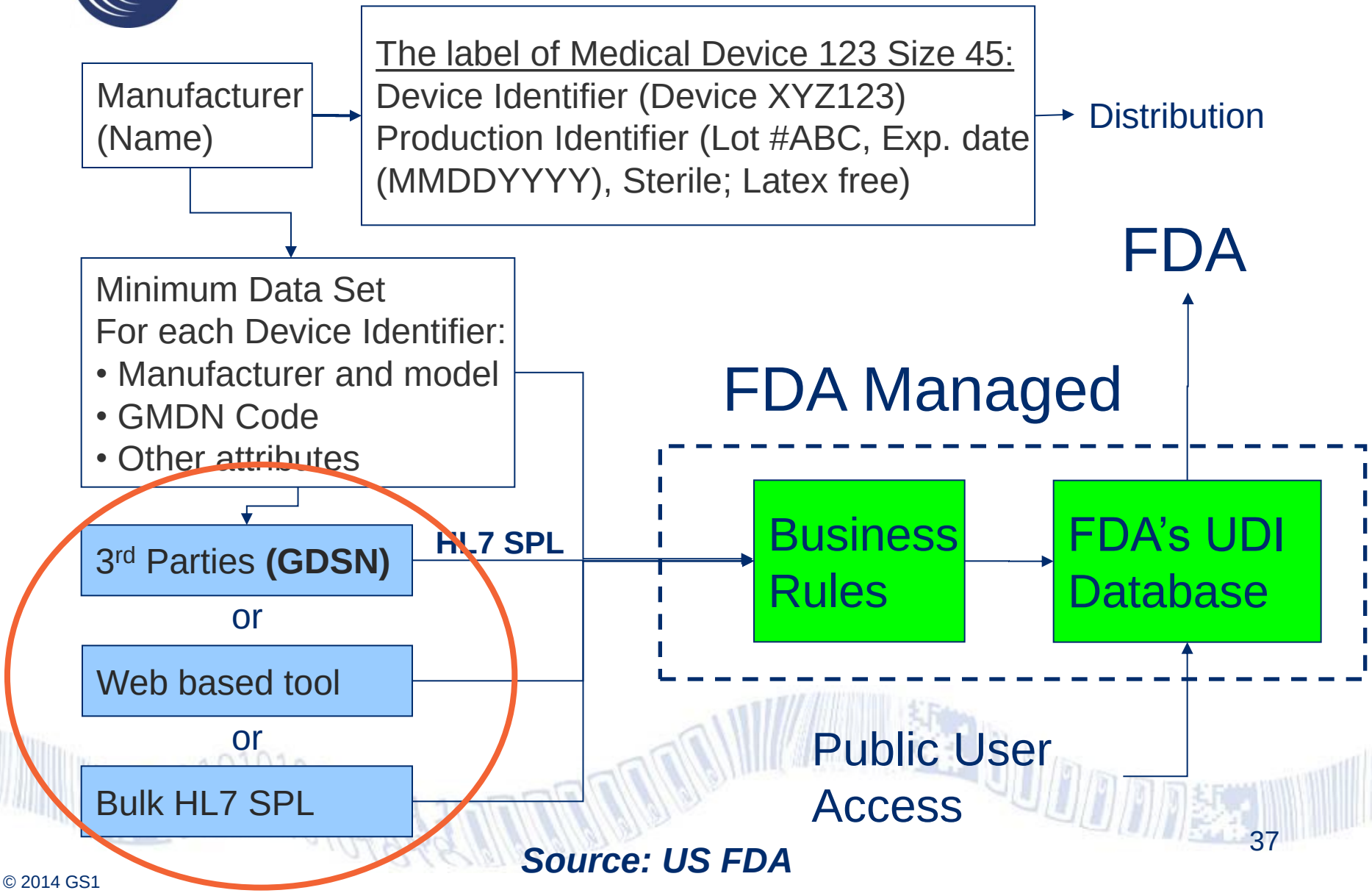
Global core data elements defined by IMDRF



Additional local data elements defined by the FDA

- DUNS no
- Authorization no (510k)
- Product Code
- FDA Listing no
- Product exempt from PMA
- Prescription product
- Kit product
- Combo product
- Contains human cell / tissue
- MR saftey
- …

GDSN is one of the third parties options to feed data into GUDID



Source: US FDA

Master Data Management and Governance

Data Quality

Data Management

Data Governance

Roles and Responsibility

Every manufacturer needs to have a Master Data Management and Governance process in place

Key Steps to Load Data into GUDID

Standard Project Management

- Obtain sponsor, funding, prioritization
- Understand the requirements, education
- Assemble the multi-functional team, leader(s)

UDI Project Management

- Determine solution path
- Understand your Validation approach
- Select solution providers (if applicable)
- **Find, collect, clean, store data attributes**
- Publish data attributes to the U.S. FDA's GUDID
- Address any error messages
- Create ongoing standard operational procedures (SOP's)

Managing Master Data
Let's not forget about the Hospital!

Supplier = data source

Needs single point-of-entry

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

Needs security

- Authorization access by supply chain partners

Standards-based

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

Hospital = data recipient

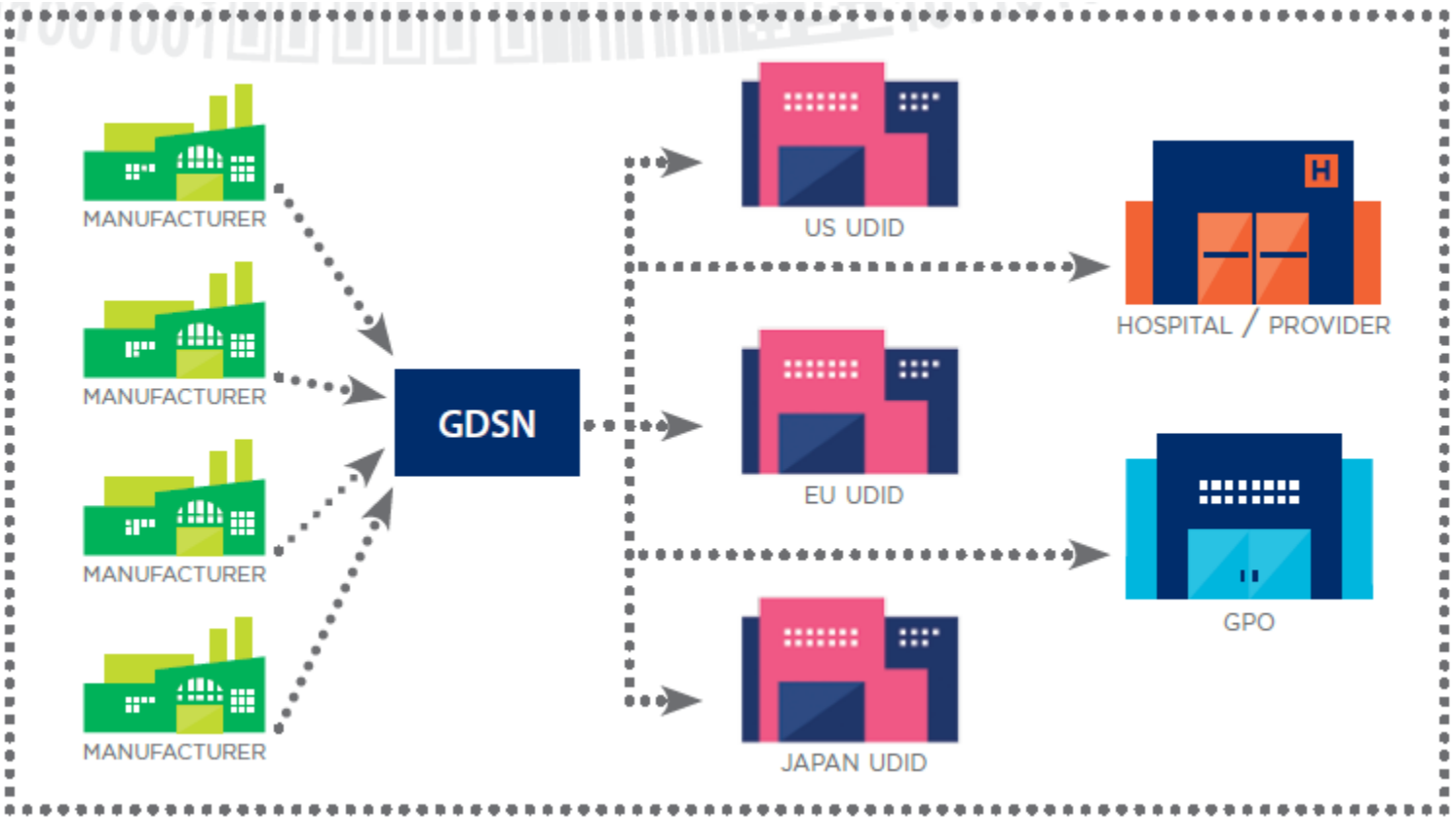
Needs single point-of-truth

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

Standards-based

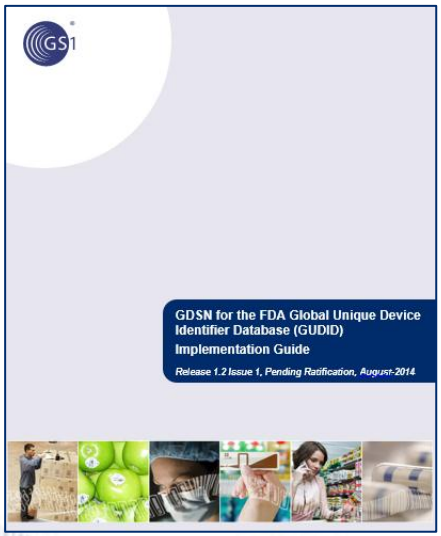
- Standard identification keys
- Consistently formatted information
- Complete information

GS1 Recommendation to the industry: Use GDSN



Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.

The most important documents



Contains Nonbinding Recommendations

Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 27, 2014.

The draft of this document was issued on September 24, 2013.

This document supersedes Global Unique Device Identification Database (GUDID), June 11, 2014.

For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: udi@fda.hhs.gov. For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification

Food and Drug Administration

Global Unique Device Identification Database (GUDID)

Health Level 7 (HL7) Structured Product Labeling (SPL) Implementation Specification
Version 1.2

http://www.gs1.org/healthcare/udi

WHAT IS UDI?

- UDI: purpose
- UDI: scope
- US FDA UDI system at a glance

WHERE IS UDI? WHEN IS UDI?

- UDI developments worldwide
- The need for a global approach to UDI

HOW TO IMPLEMENT UDI?

- How do the GS1 standards support the UDI requirements?
- AIDC Translation of UDI
- GDSN and Data Management

KEY CHALLENGES

For the industry

- Labelling
- Database elements and maintenance

Main questions asked by the industry

- What does my company produces?
- What is the scope of UDI?
- What class is my device?
- Can my product be considered as a kit?

- Who is the « labeler » according to the U.S. FDA definition?

- On which packaging level must the UDI be applied?
- Does my devices have to be directly marked?

Challenges faced by the industry on the GUDID

PROJECT ORGANIZATION

- What is the mission?
- How big is the project - Who, What, When?
- Who will the U.S. FDA call at the manufacturer if the data is not in the UDI database on time?
- What is the real duration?
- What is the deadline and how do you meet it?
- How do we structure the data?
- How do we control cost?
- What does being *finished* look like?

RESOURCES

- How do we identify the resources?
- How do we secure them?
- How do we educate them?

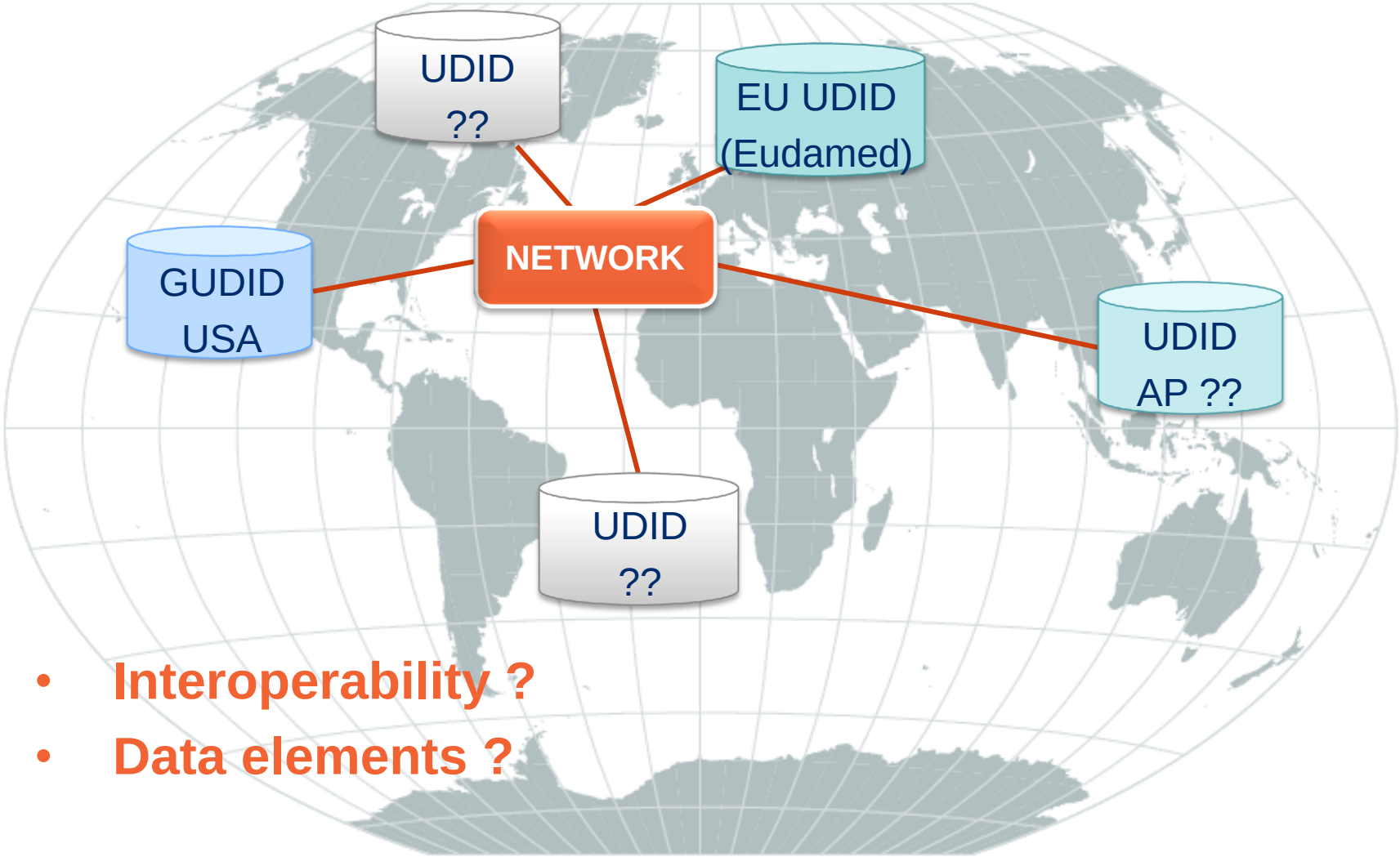
DATA

- What data do we need?
- How do we manage it?
- Who has it/owns it?
- What format is it in?
- How do we convert it?
- Can we trust it?
- How to digitize it?
  (Manually, copying, scanning)

SOLUTION

- How many products does your company sell in the U.S.?
- Does your company already submit new product introductions to the U.S. FDA via internally supported processes?
- What is your company's expertise in the UDI requirements? GS1 Standards?
- How will your company respond to sharing data with third parties? (legal, purchasing, regulatory, quality, commercial, IT)

UDID – Open questions



- **Interoperability ?**
- **Data elements ?**

How to get information on UDI?

http://www.gs1.org/healthcare/udi

How to comply with Unique Device Identification (UDI)

GS1, received on 17 December, 2013 accreditation by the U.S. Food and Drug Administration (FDA) as issuing agency for unique device identifiers (UDIs).

Global GS1 Standards meet the government's criteria for **UDIs** and will help manufacturers comply with the requirements of the new **FDA UDI regulation**, which was published in September 2013 to support patient safety and supply chain security.

To find out more, read the FAQ's.

Introduction

The IMDRF (International Medical Device Regulator Forum), the United States Food and Drug Administration (FDA) and the European Commission are aiming for a globally harmonised and consistent approach to increase patient safety and help optimise patient care by proposing legislation for **Unique Device Identification (UDI)**, using GS1 standards.

What is UDI?

The Unique Device Identifier (UDI) is a system used to mark and identify medical devices within the healthcare supply chain.
The U.S. FDA released 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** 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.

UDI should be applied to all **medical devices** available on the market. Download here the GHTF document which defines the term "**Medical Device**".

The implementation of UDI can enhance patient safety and improve efficiency in the healthcare supply chain. The system is expected to unambiguously identify medical devices allowing for more accurate reports of adverse events, manage recalls more effectively, reduce medical errors and provide for a secure global distribution chain.

As part of the **UDI system**, the FDA is also creating the Global Unique Device Identification Database (GUDID) which will include a standard set of basic identifying elements for each device with a UDI. Manufacturer's will be responsible for submitting and maintaining their own data in the database.
Read how Global Data Synchronisation enables the Unique Device Identification.

GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guide

Advantages of GS1 Standards for the implementation of UDI

A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide. **A single standard ultimately accelerates implementation and increases compliance to the UDI regulations.** Read the McKinsey & Company report, "Strength in Unity", which demonstrates

Want to know more? Download our UDI leaflets:

The fundamentals of UDI

Global Data Synchronisation and UDI

The need for global standards

Healthcare is **local**

- Healthcare providers are local
- Regulations are local

Healthcare is **global**

- Healthcare supply chains often cross borders

Country-by-country solutions are not sufficient nor effective

A global harmonised approach and implementation is needed

Contact Details

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