The Global Language of Business

Update on GS1 and UDI

23rd AHWP Annual Meeting Program

22 – 25 October 2018, Kuala Lumpur, Malaysia

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- GS1 Standards
- GS1 for harmonised implementation of UDI
- Time for change is NOW…
- Contact details

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GS1 Standards

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GS1 – a global non-for profit standard organisation

1 million	150 countries	6 billion	112 MOs
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 6 billion times per day globally	112 Member Organisations around the world

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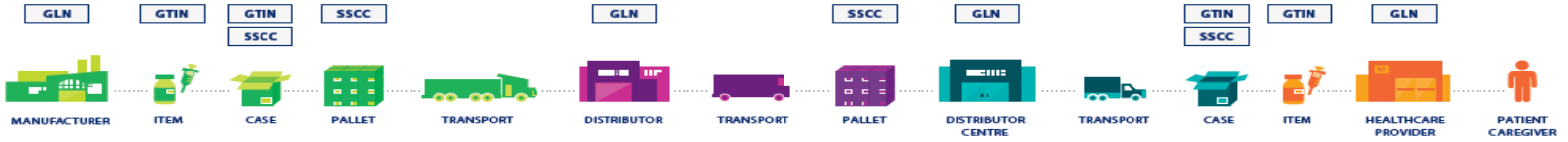
A global system of standards to ensure visibility

Identify

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

Capture: GS1 standards for automatic identification and data capture

GS1 BARCODES **GS1 EPC/RFID**

EAN/UPC GS1-128 ITF-14 GS1 DataBar GS1 DataMatrix EPC HF Passive EPC UHF Passive

Share

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)

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GS1 standards for harmonized implementation of UDI

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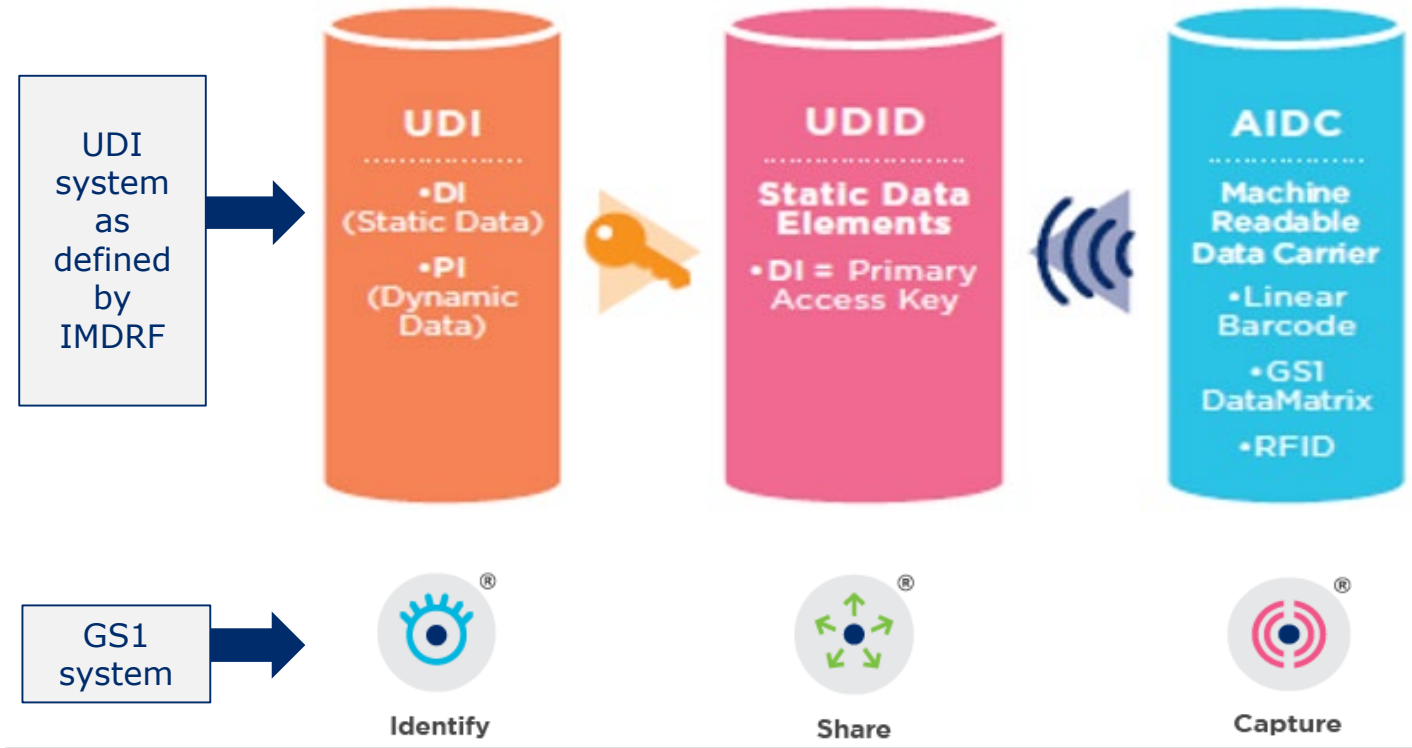
UDI system and GS1 system



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UDI in AIDC terms

Identify

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**

The **HRI format** shall follow the rules of the UDI Issuing Agency

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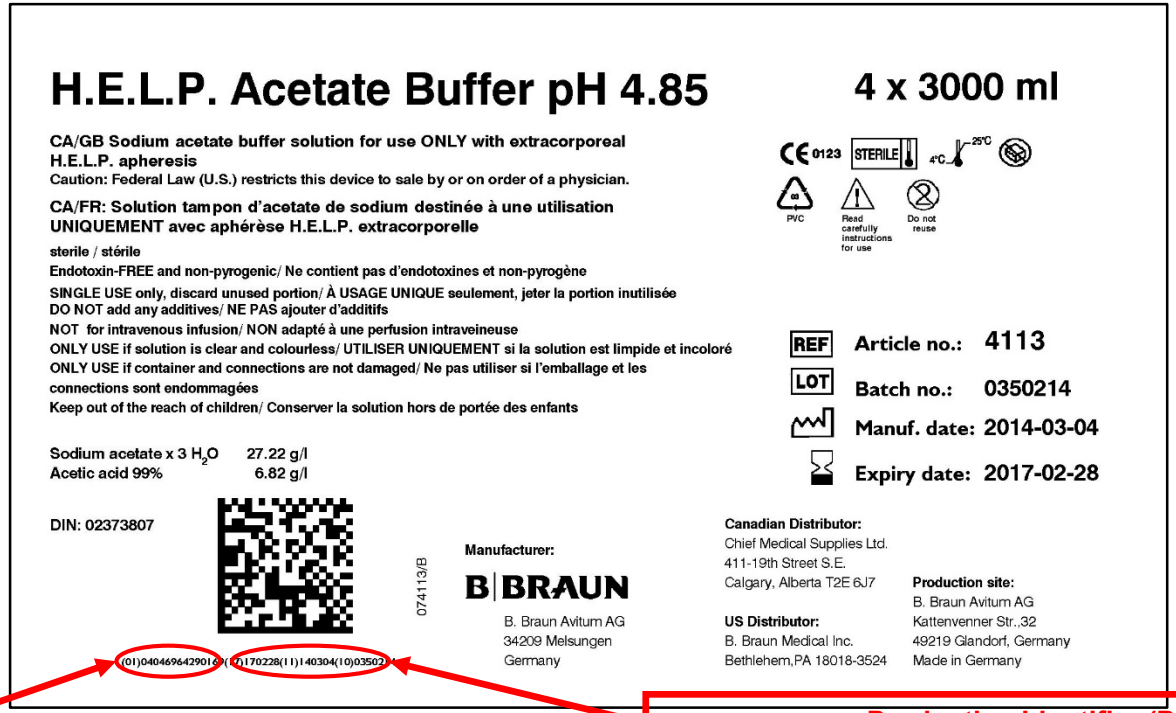
UDI Example of label

Capture



Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

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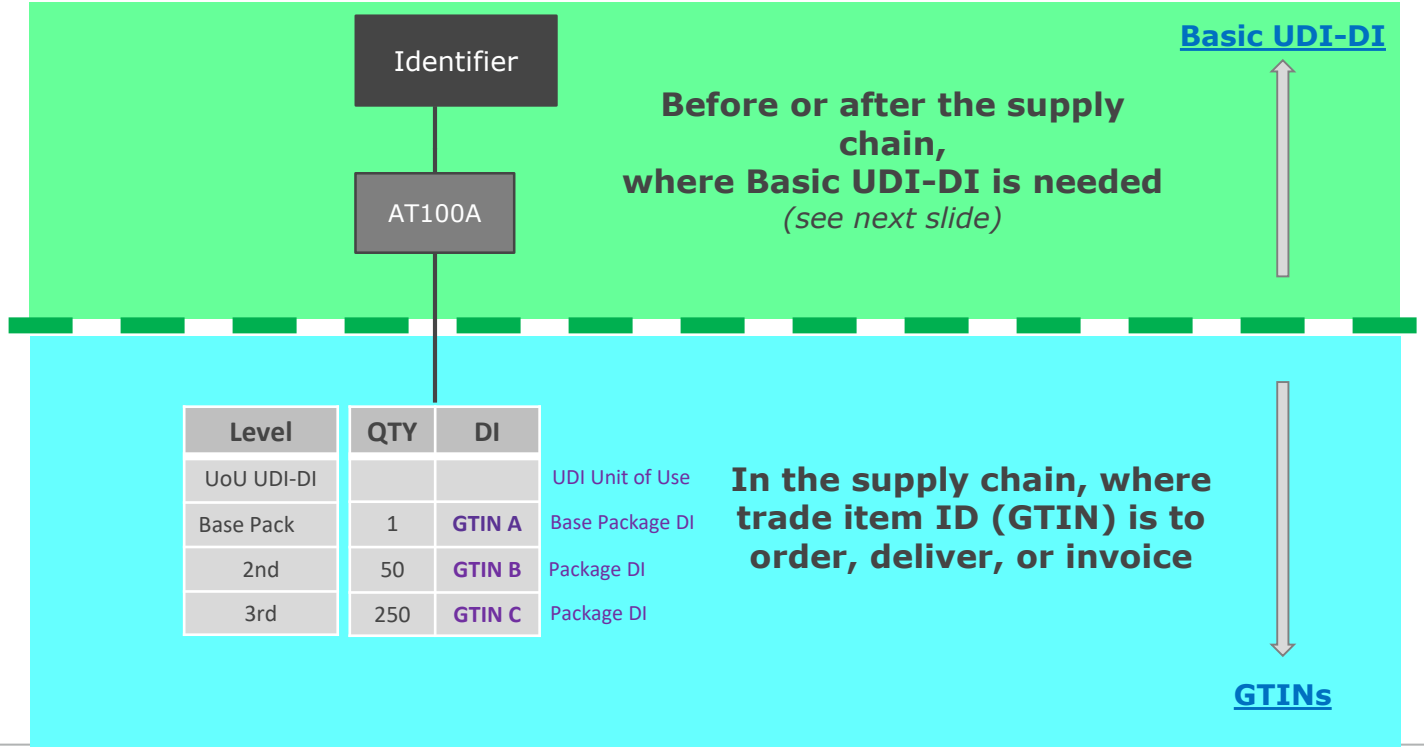
NEW : EU specificity: “Basic UDI-DI” for illustration only



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NEW GS1 Standard : "Global Model Number" to support implementation of the Basic UDI-DI

- GS1 Company Prefix + a model reference
- Model reference number: manufacturers internal numbers, can be alphanumeric

GS1 Company Prefix		Model Reference Number	
N_1 ...	N_i	X_{i+1} ... variable length...	X_j
Total length up to 30 characters			

- In healthcare:
  - data title: "BUDI-DI"
  - for medical device registration
  - independent of packaging
  - never used in a data carrier

***Example** of Basic UDI-DI on regulated documentation:*

BUDI-DI: 5149854J856M

Data title | GCP | Model ref. number

- GS1 implementation guide to be drafted in 2018-2019, based on the EU Commission guidelines

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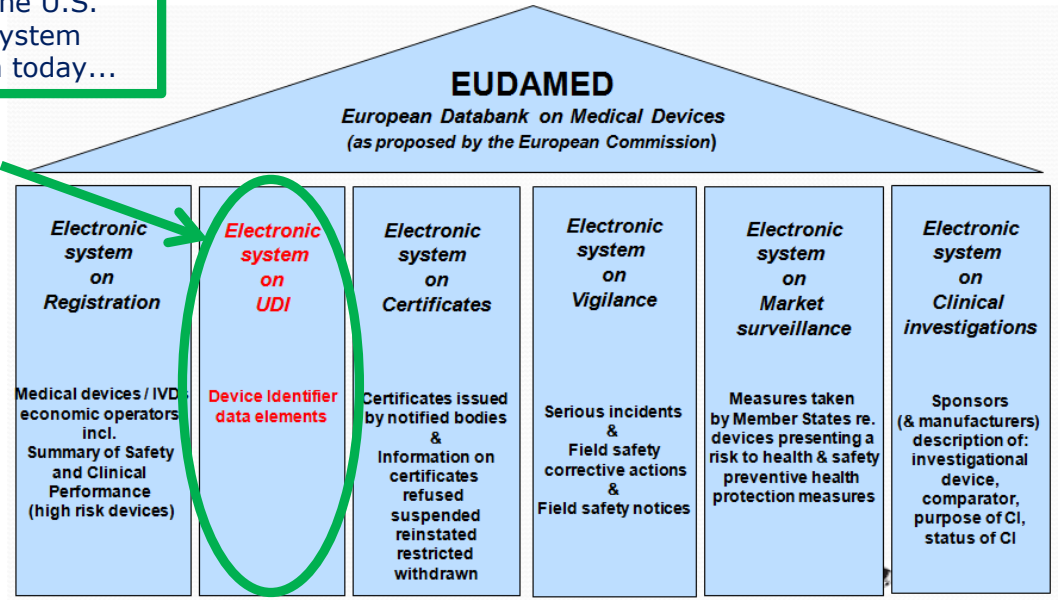
UDI Databases – USA and EU

Part that the U.S. FDA UDI system focuses on today...



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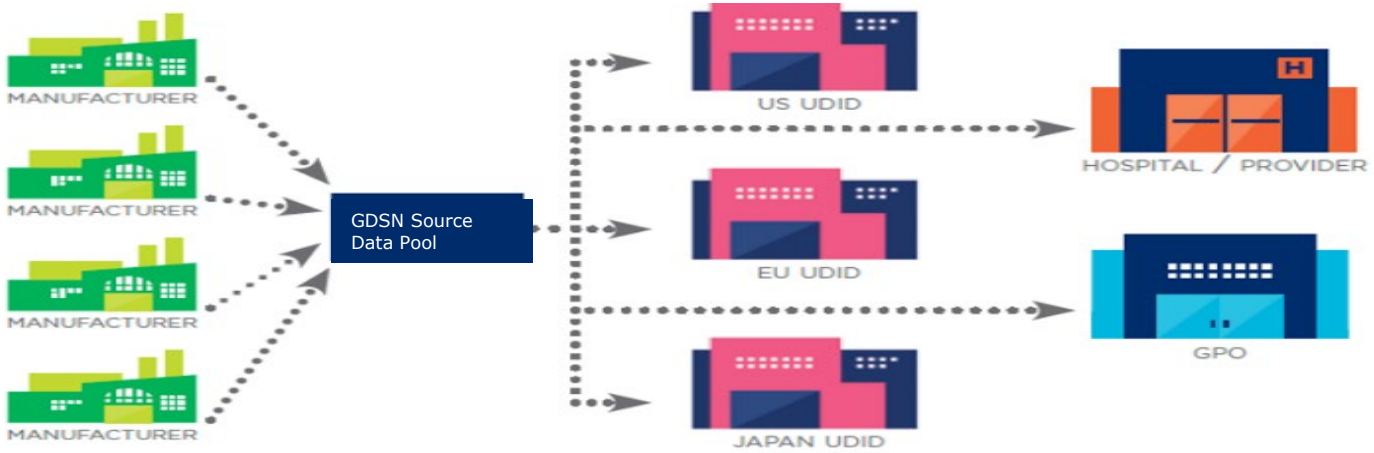
Managing data and global standards: Global Data Synchronisation Network (GDSN)



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

Mapping of GDSN data elements with EUDAMED will start when technical specifications will be released by the EU Commission

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Time for change is NOW …

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Developments and requirements for UDI

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GS1 key to implement requirements on medical devices

Accredited as UDI Issuing Agency by the US FDA

99% of medical devices identified with GTIN in Japan

MHLW Annual Survey, 2012

UDI assigning entities listed in the EU MDR

Mandated by ANMAT for traceability of certain devices in Argentina

£3 million on average saved each year in every NHS hospital in England

Lord Carter interim report, 2015

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

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The benefits of UDI

Manufacturers:

- cost optimization
- data synchronization
- process efficiency

Hospitals:

- adequately identified medical devices
- single and integrated system of information management

Regulators:

- higher levels of market surveillance
- more efficient adverse event reports and quicker recall - also across borders

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The need to align on a global UDI framework

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

  This will ensure :
  - highest levels of patient safety beyond borders
  - harmonized identification systems for medical devices globally

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34th Global GS1 Healthcare Conference

30 October to 1 November 2018 - Bangkok, Thailand

- Traceability, UDI and global regulatory developments
- Success stories of implementations from manufacturers, wholesalers and hospitals – experiences & benefits
- Patient safety and quality of care – how to improve those
- Awards for best hospital implementations
- And much more…

SAVE THE DATE!

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

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