



Global standards for a safer and more efficient medical devices supply chain

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AHC-AHWP Joint Workshop
18 - 19 November 2014, Seoul - Korea



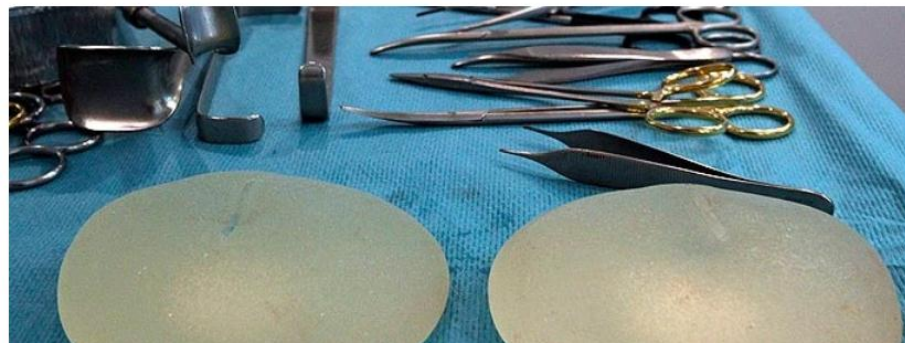


Lack of standards in daily life can cost money and time ...





...in Healthcare it can cost a life



PIP breast implants: A ruptured disaster



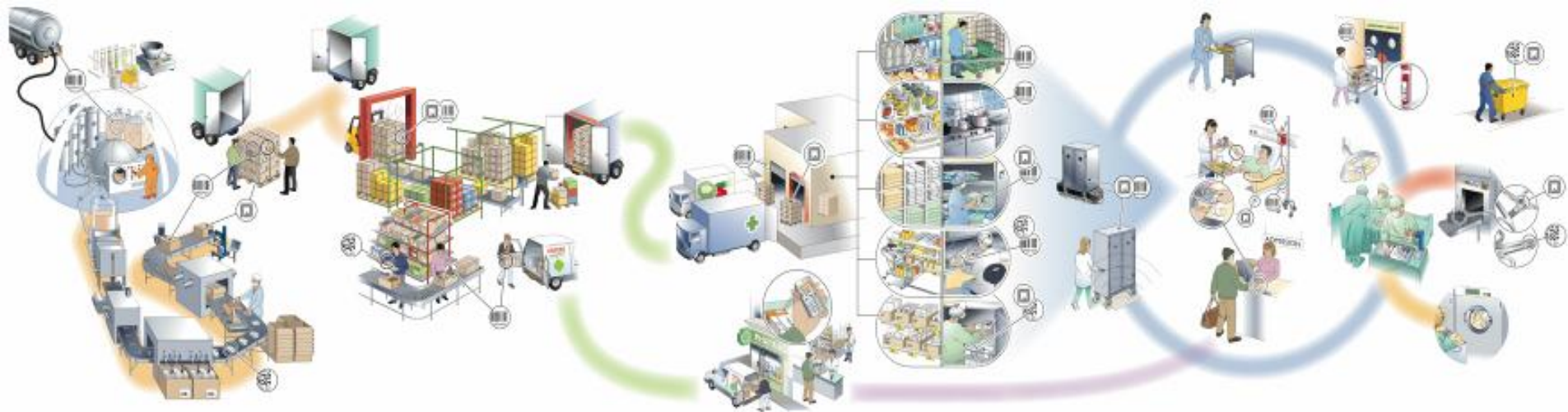


The need for **global standards**

- **Manual interventions** in the healthcare supply chain decrease its efficiency and accuracy
- **Product recalls** can be difficult to manage, in particular for healthcare providers
- **Traceability** from manufacturer to patient is problematic
- **Counterfeiting** is an increasing global threat
- **Errors in hospitals** can result in additional treatments, disabilities or even loss of life
- Product/patient relationship in **electronic health records** (EHR) and registries is complex and manually captured



GS1 Global Healthcare User Group



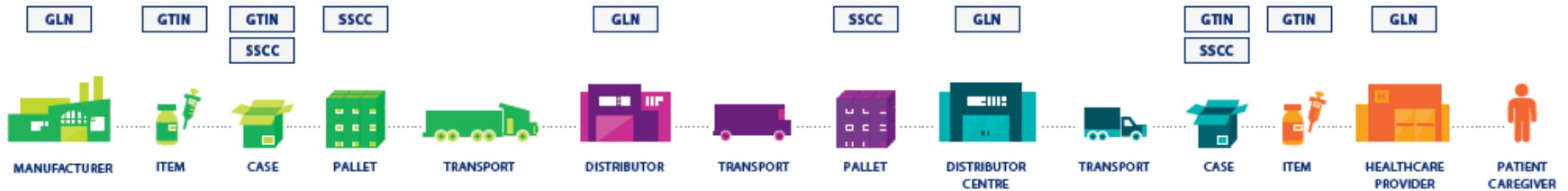
To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.



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

EAN/UPC



GS1-128



ITF-14



GS1 DataBar



GS1 DataMatrix



GS1 EPC/RFID

EPC HF Passive



EPC UHF Passive



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)





The basics of GS1 system

The 3 G's ... to support Identify, Capture and Share

Global Trade Item Number	GTIN®	Product Identification
Global Location Number	GLN	Location Identification
Global Data Synchronization Network™	GDSN®	Data Attribute Accuracy

1234567891234





What information could be standardised?

Product Master Data, such as:

- unique and unambiguous **identifiers**
- harmonised **descriptions**
- supporting **regulatory** requirements implementation
- facilitating exchange of **logistics information**

Purchasing Information, such as:

- **Shipping** locations
- **Logistics** identifiers
- **Pricing** information





What could it mean for you?



Manufacturers: cost optimisation, data synchronisation and process efficiency



Hospitals: adequately identified medical devices and a single and integrated system of information management



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

Global standards enable **safer and more efficient supply chain** to ensure that the **right device** is available at the **right place** and the **right time** for the **right patient**.



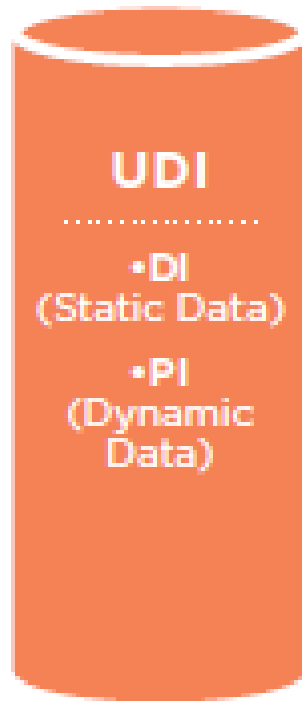
Example: the US FDA UDI system

UDI brings... Global Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information



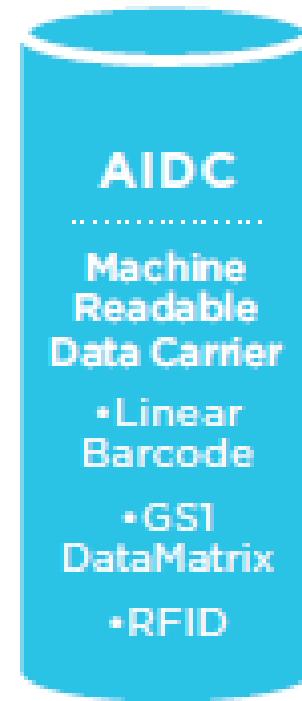
UDI system at a glance



Unique Device Identification



Global Unique Device Identification Database



Automatic Identification and Data Capture

DI = Device Identifier

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



GS1 UDI issuing agency for the US FDA

GS1 was accredited as issuing agency by the FDA

Meaning that the GS1 system can be used by medical device manufacturers to identify and mark their products and to deliver the requested product information to the FDA GUDID database,

UDI Issuing Agencies

An issuing agency is an FDA-accredited organization that operates a system for assignment of UDIs according to the final rule. The final rule permits multiple issuing agencies and provides a process through which an applicant would seek FDA accreditation as an issuing agency. See [21 CFR 830 Subpart C](#).

Applicants seeking initial FDA accreditation as an issuing agency shall notify the FDA via email at udi@fda.hhs.gov.

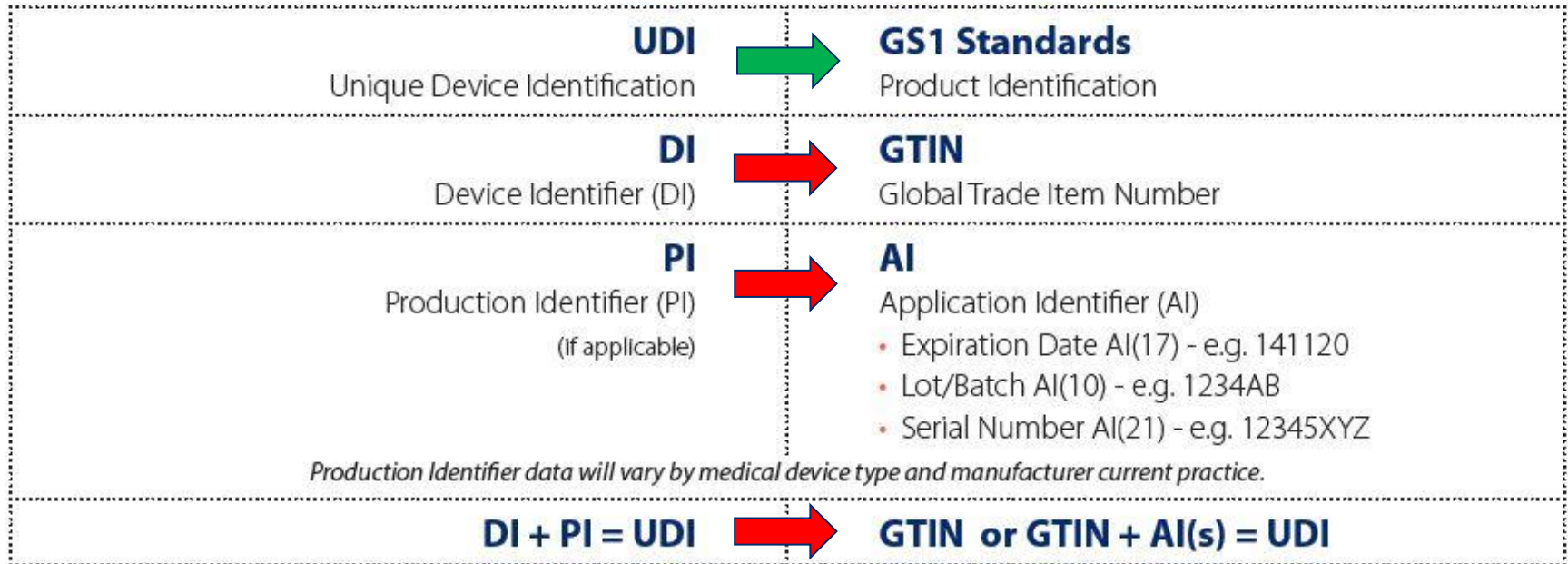
FDA has accredited the agencies listed below:

1. Firm Name: **GS1**
Address: **Princeton Pike Corporate Center, 1009 Lenox Drive, Suite 202, Lawrenceville, NJ 08648**
Contact Person: **Siobhan O'Bara, Senior Vice President - Industry Engagement**
Phone: **(609) 620-8046**
Email: sobara@gs1us.org
Web Site: <http://www.gs1.org>
Date of Initial Accreditation: **December 17, 2013**
Initial Accreditation Granted through: **December 17, 2016**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm>

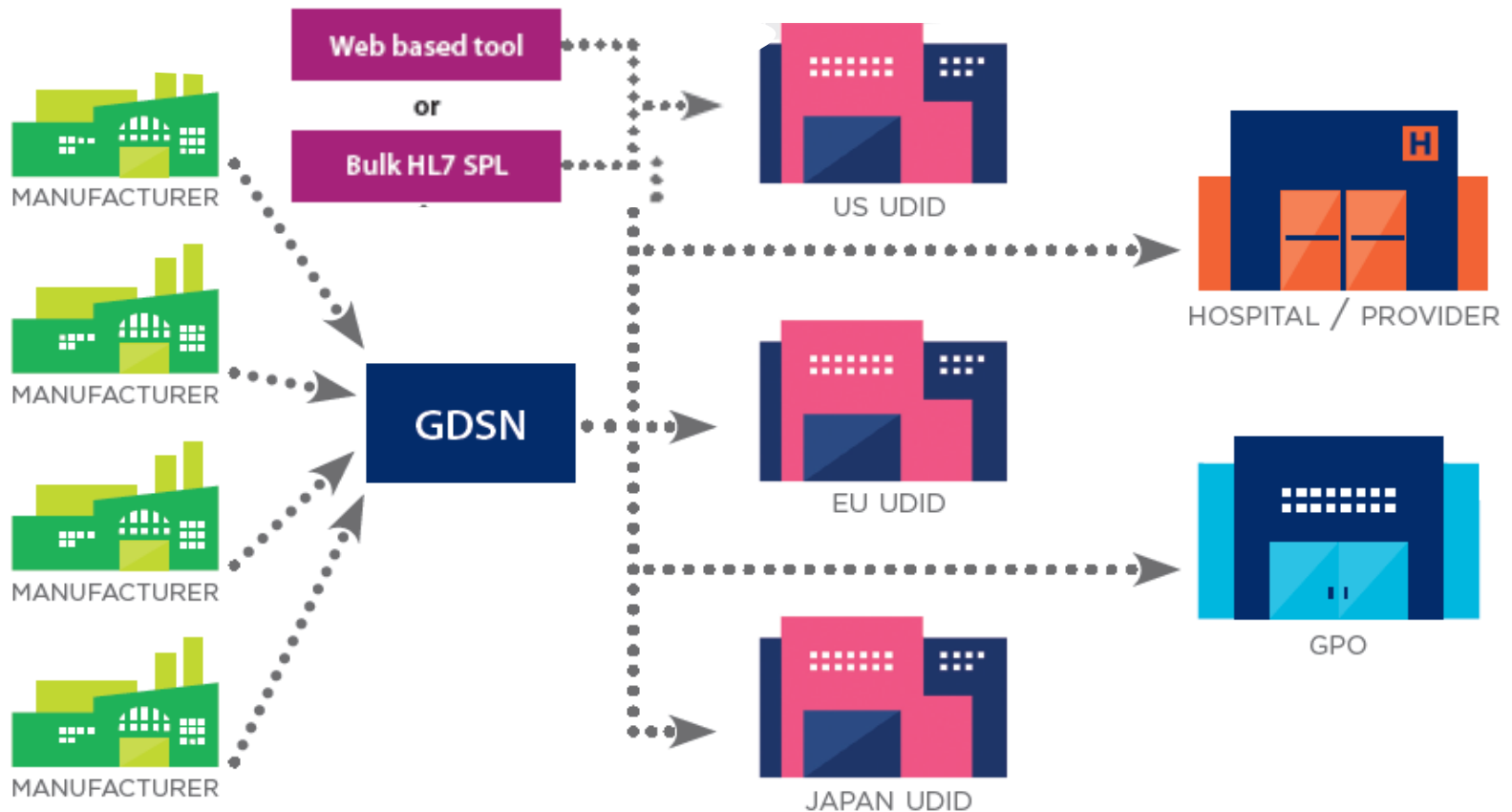


UDI in GS1 terms





The industry uses GDSN to populate the GUDID



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



Example: the UK NHS Procurement



Department
of Health

NHS
England

**“WE WILL MANDATE THROUGH
CONTRACTS THE USE OF GS1
CODING IN THE NHS”**

A Procurement Development
Programme for the NHS



Exemple: GS1 for MD traceability in Argentina

- 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



GS1 endorsed by 60 stakeholders



Global Healthcare Stakeholders Support the Adoption of GS1 Standards

GS1 Global Standards can become the ONE language of choice for supply chain management and electronic commerce in Healthcare and can improve patient safety, patient care and will support electronic health records. GS1 Global Standards ensure compatibility of supply chain solutions, not only within an organisation but also across country, region, and across sectors and borders.

The McKinsey white paper clearly lays out the case for global standards in Healthcare and encourage all industry stakeholders worldwide, including manufacturers, distributors, and regulators to adopt the GS1 global System of Standards and realise improved patient care and reduced overall Healthcare costs.

The GS1 System of Standards provides an effective globally harmonised and integrated framework to manage supply chain information. The undersigned organisations strongly endorse and support GS1 usage and implementation.



B. Braun/Meloyers AG
Dr. Michael Leggen
Member of the Board (Division Hospital Care & USFM)



Johnson & Johnson Health Care
John F. Hogan
President, Johnson & Johnson Health Care



Abbott
A Promise for Life
Cathy S. Mauer
Senior Vice President, Quality Assurance, Regulatory and Engineering Services



COVIDIUM
Matt Gattuso
President, Global Health Systems



Global Healthcare Stakeholders Support the Adoption of GS1 Standards



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New McKinsey & Company report quantifies supply chain issues in Healthcare



New McKinsey report “Strength in unity: The promise of global standards in healthcare”

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:

<http://www.gs1.org/healthcare/mckinsey> or

http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

Source: <http://www.mckinsey.com>





Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

- “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”
- [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)
- “Rolling out such standards-based systems globally **could prevent tens of billions of dollars’ worth of counterfeit drugs** from entering the legitimate supply chain”

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



The need for alignment and a global framework

Healthcare is **local**

Healthcare providers are local

Regulations are local



BUT country-by-country solutions are not sufficient nor effective

Healthcare is **global**

Healthcare supply chains often cross borders

A global harmonised approach and implementation is needed



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<http://www.gs1.org/healthcare>

