



# GS1 Healthcare

Raising the bar on patient safety  
and supply chain efficiency





## Transforming the Healthcare supply chain

Healthcare systems around the globe are facing challenges that affect the entire supply chain, from manufacturers through to wholesalers, distributors, group purchasing organisations and healthcare providers. Everyone is concerned primarily with two main issues: **increasing supply chain efficiency and, more importantly, ensuring patient safety.**

The regulatory landscape continues to evolve; new regulations will have a direct impact on the Healthcare supply chain, requiring stakeholders to implement automatic identification technologies, electronic product catalogues, serialisation (a unique serial number on each package or product, where appropriate) and/or traceability systems.

Supply chain data standards can provide a global framework for all stakeholders to comply with regulatory and tender requirements and to meet the challenges of today's complex Healthcare supply chain.



The GS1 System of Standards provides a global harmonised and integrated framework to manage supply chain information.



# Meeting the challenges of today's Healthcare supply chain

**Concerns about patient safety and rapidly escalating Healthcare costs have called for authorities and all stakeholders to take action to address important challenges:**

- Reducing medical errors
- Enabling effective product recalls, adverse event reporting and post market surveillance
- Increasing supply chain security and fighting counterfeiting
- Facilitating treatment documentation in Electronic Health Records/ Electronic Medical Records (EHR/EMR)
- Optimising production and packaging processes in a global environment
- Optimising supply chain management, including logistics, procurement, stock and asset management processes

**Notable example of regulatory developments worldwide include:**

- Unique Device Identification (UDI) & traceability: US FDA, Global Harmonization Taskforce (GHTF), European Commission, China SFDA...
- Serialised pharmaceutical product identifier & traceability: US FDA, Turkey, Brazil, California...
- GS1 DataMatrix: France, Korea, Turkey...
- Electronic product catalogues: Australia, NHS (UK), Turkey...

## Did you know?

- 1.3 million patients are injured annually because of medication errors in the USA (Source: The Prescription, Vol. 1, No. 1, July 2005, Medication Error Statistics)
- A batch of 70,000 fake life-saving drugs entered the National Health Service (NHS) in the UK in June 2007 (Source: Medicines and Healthcare Products Regulatory Agency, UK)
- Of approximately 66,000 adverse event reports received by the FDA in the United States, 60% lacked the lot number or other meaningful identifier (Source: FDA)
- Three different (country specific) bar code requirements could cost some manufacturers an additional €38 million per year in Europe alone (Source: EFPIA – assuming production of 500 million packs in Europe per year and three different product ID requirements)
- The average Healthcare provider is spending over 30% of its annual operating budget to support the supply chain (Source: University of Arkansas)



## Pushing the boundaries of the Healthcare supply chain

**Managing supply chain data – Increase visibility and security in the Healthcare supply chain**

- Automatic Identification & Data Capture (AIDC) systems, including bar codes and RFID
- eProcurement, enabled by Electronic Data Interchange (EDI)
- Electronic product catalogues
- Traceability Systems

# Why choose the GS1 System of Standards

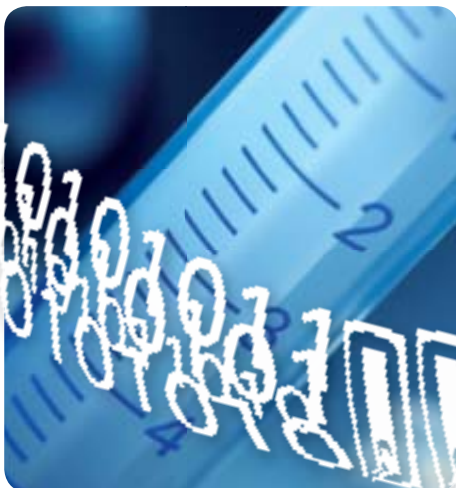
## Reduce cost and complexity

Some organisations develop their own proprietary identification systems, electronic product catalogues or traceability systems, which are only functional within their own organisation. Others use locally developed systems that are only functional within the confines of a single sector or a single country.

The GS1 System of Standards enables all stakeholders to efficiently and effectively comply with various local and global requirements by ensuring interoperability and compatibility within an organisation, between organisations and across borders.

- 1. Global** – GS1 Standards ensure globally unique identification and enable cross-border compatibility of supply chain solutions.
- 2. Robust** – Today, in various sectors, over 6 billion transactions per day are enabled by GS1 Standards, demonstrating its robustness.
- 3. Multi-sector** – Using the same standard to identify and trace Healthcare and non-Healthcare items ensures compatibility for Healthcare stakeholders sourcing a wide variety of items.
- 4. User-generated** – GS1 Standards are built and maintained collaboratively by volunteers from across the world and representing every part of the supply chain.
- 5. Scalable** – GS1 Standards meet the needs of a small rural hospital as well as a multi-national supplier.

Many leading organisations worldwide have endorsed GS1 Standards to enable effective and efficient supply chain solutions for the Healthcare sector.





“We need a global vision: Healthcare is a global business where supply chain partners exchange goods and information. Global standards are key success factors for process improvements for suppliers.”

**Dr. Meinrad Lugan, Member of the Management Board of B.Braun Melsungen AG, Germany**

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“Using multiple standards to catalogue, order, invoice, inventory and ship supplies and devices, increases costs and safety risks and makes the Healthcare supply chain so complex that efficiencies are difficult to achieve.”

**Mike Duke, Senior Director, Supply Chain Services, VHA, Inc., USA**

(VHA serves 1,400 not-for-profit hospitals and more than 24,000 non-acute care Healthcare organisations nationwide.)

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“We are taking this leadership position now because it is time to implement GS1 Global Supply Chain Standards in Healthcare if we hope to; reduce the overall cost of Healthcare, significantly increase supply chain efficiency and improve patient safety. GPOs stand ready to help their hospitals and supplier partners make Healthcare better today!”

**Curtis Rooney, President of the Health Industry Group Purchasing Association (HIGPA), USA** (representing 16 Group Purchasing Organisations)

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“When developing a bar code strategy, reviewing a company’s existing bar code strategy or changing packaging and labelling configurations, Eucomed recommends that its members consider the adoption, or increased use of GS1 Standards.”

**Eucomed Guidance Document, September 2007** (Eucomed represents 4,500 designers, manufacturers and suppliers of medical technology.)

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“CPSI and ISMP Canada jointly endorsed the adoption of the GS1 Global Standards for automatic identification of pharmaceutical products in Canada. Through the Canadian Pharmaceutical Bar Coding Project, the Healthcare system is working to proactively and cooperatively reach agreement on implementation of the standards, moving towards use of bar coding to enhance safety checks at multiple points...”

**Canadian Patient Safety Institute (CPSI) and Institute for Safe Medication Practices (ISMP) Canada, Press Release, November 2009**

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“Adopting GS1 Standards will allow us to improve and integrate processes with our suppliers, distributors and customers. This system also offers improvement in security, cost savings and efficiencies.”

**Mario Jerez, Director, Cenabast, Chile (Supply Center for the Ministry of Health in Chile)**

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“We are building an electronically interconnected health environment based on GS1 Standards. This will provide a vital opportunity to make significant efficiency gains and cost savings in the public health sector at a time when there are considerable pressures on limited resources to meet current and future service demands.”

**Ken Nobbs, Project Leader, Supply Chain Efficiency, National E-Health Transition Authorities (NETHA), Australia**

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“We have recommended that the GS1 System should be used for coding in Healthcare, both by manufacturers of medicines and devices, and by NHS organisations. This recommendation will be supported by co-ordinated action from a number of agencies.”

**Lord Hunt of Kings Heath, Former Minister of State for Quality at the Department of Health (2007), UK**

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“The AHRMM Board and its membership are dedicated to the GS1 Standards movement in Healthcare because we understand the positive impact data standards will have on improving patient safety and supply chain efficiency. I urge every supply chain professional to become educated about the GS1 Standards...”

**Jay Kirkpatrick, President, Association for Healthcare Resource & Materials Management, American Hospital Association**

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## How the GS1 System of Standards works

GS1 Standards – Interoperable building blocks for an integrated system enabling traceability and visibility

The GS1 System of Standards is a flexible architecture that ensures maximum efficiency. It is built around and upon several elements:

- **GS1 Identification Keys** are the foundation of the GS1 System and ensure the globally unique identification of products, locations, assets, etc. Identification Keys include for example GTIN (Global Trade Item Number) and GLN (Global Location Number).
- **GS1 Application Identifiers** present a standardised way to encode additional information, such as expiry date, lot number and serial number.
- **GS1 BarCodes** provide a portfolio of data carriers including GS1-128 Linear bar codes, GS1 DataMatrix (two dimensional bar codes) and others. For manufacturers, these meet the various needs including; differing pack sizes, amount of data and packaging/production rates. For users, these carriers can include all the required data.
- **GS1 EPCglobal** uses Radio Frequency Identification (RFID) technology to electronically carry GS1 Identification Keys in the Electronic Product Code (EPC)
- **GS1 eCom** enables Electronic Data Interchange, providing clear guidelines for creating electronic versions of all sorts of business documents in the Order to Invoice cycle, such as Purchase Order (PO) and Despatch Advice (DESADV), based on GS1 Identification Keys.
- **GS1 Global Data Synchronisation Network (GDSN)** allows users to obtain, maintain, validate and exchange master data in a secure and reliable environment via a network of GDSN-certified data pools. The synchronised information (including GTIN, GLN and a defined set of product attributes [elements]) empowers electronic product catalogues.
- **GS1 EPC Information Services (EPCIS)** provides the ability to track and trace products as they move through the supply chain, and includes a set of interfaces (capture and query) for obtaining and sharing data about unique items both within and across organisations.

Standards-based solutions for the Healthcare supply chain

## IDENTIFY

### GS1 Identification Keys & Attributes

Product	Location/Legal entity	Logistic unit	Asset	Document
Global Trade Item Number (GTIN)  Optional GTIN attributes such as lot number, serial number, expiration date	Global Location Number (GLN)	Serial Shipping Container Code (SSCC)	Global Returnable Asset Identifier (GRAI)  Global Individual Asset Identifier (GIAI)	Global Document Type Identifier (GDTI)



## CAPTURE

### GS1 BarCodes and EPCglobal RFID

EAN/UPC	ITF-14	GS1 DataBar	GS1 DataMatrix	EPC/RFID
<b>GS1-128</b> 				



## SHARE

Master data	Transactional data	Physical event data
Global Data Synchronisation Network (GDSN)	Electronic business messaging GS1 XML or EANCOM	EPC Information Service (EPCIS)

Connecting the dots from point-of-production to point-of-care or point-of-dispensing

### About GS1 and GS1 Healthcare

GS1 is a neutral, not-for-profit organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day

with the GS1 System of Standards. GS1 is truly global, with local Member Organisations in 108 countries, with the Global Office in Brussels, Belgium.

GS1 Healthcare is a global, voluntary Healthcare user group leading the Healthcare sector to the successful development and implementation of global standards to enhance patient

safety and supply chain efficiencies. GS1 Healthcare consists of participants from all stakeholders of the Healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organisations world-wide. For more information, visit [www.gs1.org/healthcare](http://www.gs1.org/healthcare).



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