



**GS1 HUG™**

**Global Healthcare User Group**

Working together to improve Patient Safety



# GS1 An Overview

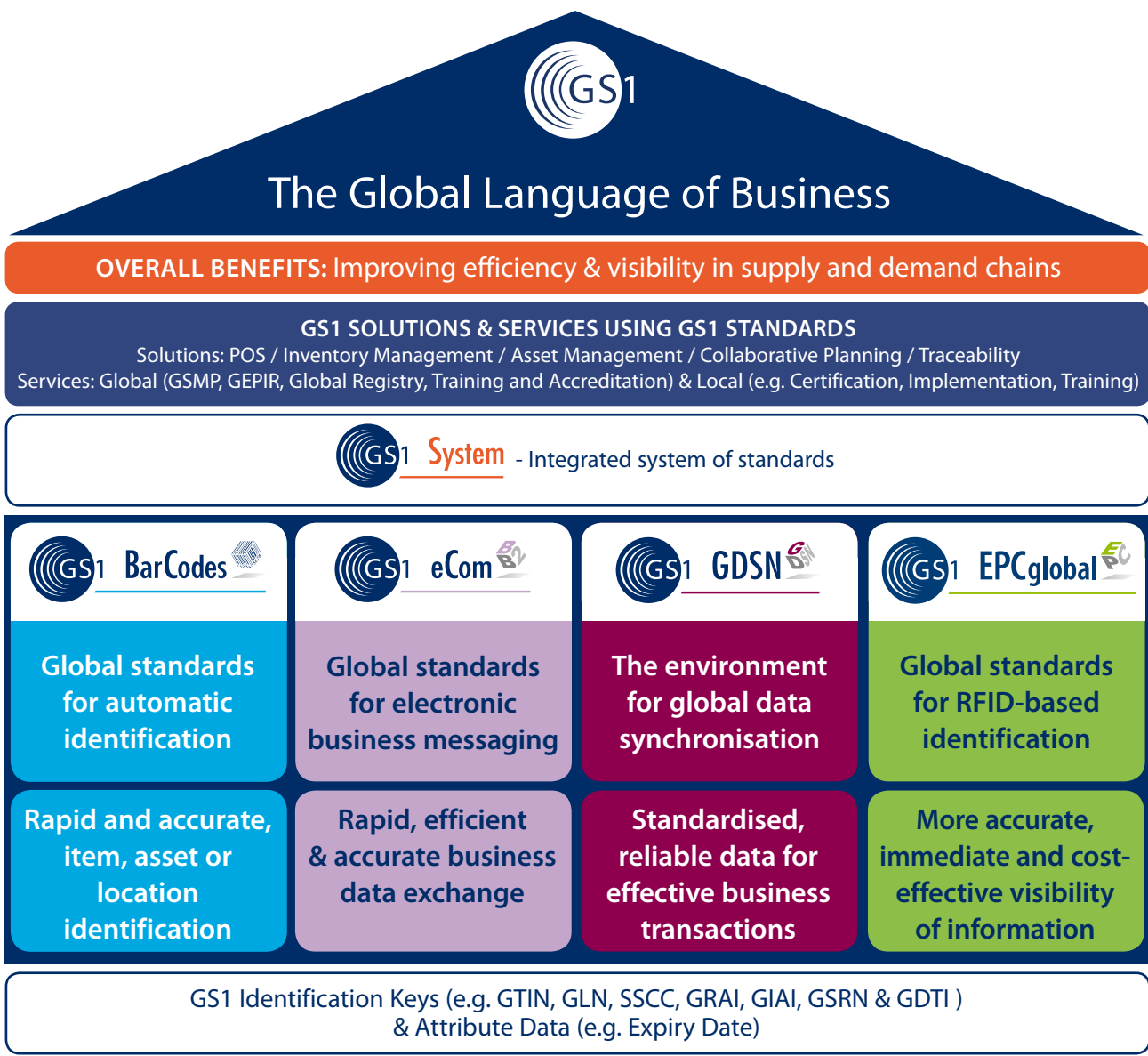
GS1 is a global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply and demand chains.

GS1 has more than 30 years experience in the development and support of global supply chain standards and technologies.

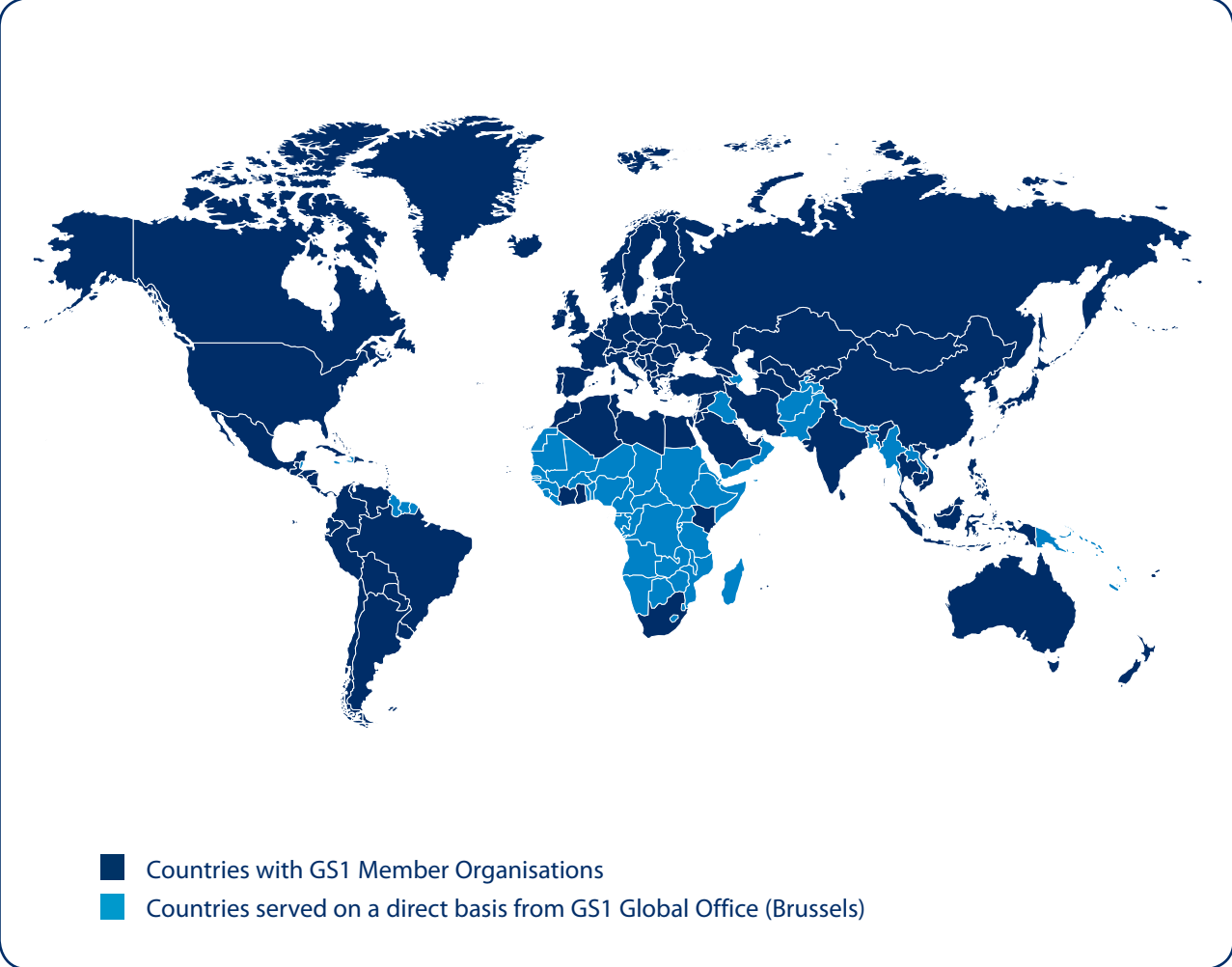
GS1 is a neutral, not-for-profit standards (and related services) organisation.

GS1 offers a diversified portfolio of products, solutions and services, including the GS1 System of Standards, the most widely used supply chain standards system in the world.

The GS1 portfolio ranges from GS1 BarCodes to GS1 eCom (electronic commerce tools) to next generation technologies, such as GS1 EPCglobal (using RFID), and solutions such as GS1 GDSN (Data Synchronisation) and GS1 Traceability.



# GS1 Around the World



GS1 operates in more than 20 industry sectors ranging from Retail, Food and Fast Moving Consumer Goods to Healthcare, Logistics and Defence.

GS1 and its Member Organisations play a leading role in supply and demand chain

management improvement worldwide for large, small and medium-sized organisations.

Formed from the joining together of EAN International and the Uniform Code Council (UCC), GS1 is truly global, with a presence in **over 104 countries** driven by

more than **a million companies** that execute over **five billion transactions each day** using GS1 standards, solutions and services.

# What is the HUG?

In May 2005, leading global manufacturing companies, from the pharmaceutical and medical devices industries, formed the GS1 Global Healthcare User Group (GS1 HUG™). It is the first time that the healthcare industry has

aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide.

The work of the HUG will help to improve the efficiency of

the healthcare supply chain for pharmaceuticals and medical devices through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices.



**Baxter**

**Johnson & Johnson**



**B. BRAUN**  
SHARING EXPERTISE

**smiths medical**  
bringing technology to life

## HUG Mission and Vision

The **mission** of the HUG is to lead the healthcare industry to the effective utilisation and development of global standards with the primary focus

on automatic identification to improve patient safety.

The **vision** of the HUG is to become the single source for regulatory agencies and trade

organisations (manufacturer, wholesaler, distributor, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

**"I'm delighted that GS1 standards will be used to improve the safety of patients worldwide while simultaneously increasing the transparency and efficiency in the healthcare supply chain. GS1 standards are already used in many countries worldwide and for many different products and services in the healthcare sector, but with the industry leadership of the GS1 Global Healthcare User Group (GS1 HUG™) we will see wide implementation and improvement globally."**

**Miguel Lopera, President & CEO of GS1.**



# HUG Objectives

The objectives of the HUG are to:

- Work with key partners in the healthcare supply chain to develop and optimise the use of global standards to ensure accurate and fast movements of goods from manufacturer to distributor, healthcare provider, hospitals or public pharmacies.
- Facilitate awareness in the healthcare sector of new technologies and methods of doing e-business.
- Provide advice and recommendations to GS1 on issues and opportunities in the healthcare sector.
- Promote best practice implementation in the healthcare area including the whole product and service portfolio of GS1.
- Promote the implementation of GS1 voluntary, global business standards throughout the healthcare sector.

**"Patient safety has many faces. A standardised machine-readable product identification can make an essential contribution to it. Where could we discuss and enhance all the related aspects better than in a global working group, which is open for all healthcare supply chain stakeholders. The GS1 HUG™ offers an excellent platform for working on harmonised solutions. We engage ourselves in this initiative with the intention to share our expertise, to learn from others and to optimise the product identification in terms of the patients."**

**Volker Zeinar, B.Braun. Former HUG Co-chair**

## HUG Focus Areas

The main focus areas for the HUG are the following:

### 1. Prevention of Medical Errors

Encoding of the unit dose or unit of use package to enable automated verification to ensure the right dose, for the right patient at the right time. Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

### 2. Product Authentication

Ensure that the packaging and associated labelling are genuine by utilising a GS1 data structure, enable authentication of individual packages, cases or pallets.

### 3. Tracking and Tracing

Utilising a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

### 4. Increase Total Supply Chain Efficiency

Through greater visibility, accuracy and velocity.

### 5. Global Standards

Work to advocate and influence the adoption of global standards for auto-identification of healthcare products using the suite of GS1 service offerings

**"AIDC is a fast developing technology which needs correct deployment on the Global scale; individual local market initiatives mean well in striving towards patient safety benefit, although it must be said, that faster and cost effective deployment with more accurate data and greater adoption will be achieved by unifying the market place based on Global Standards for Healthcare."**  
**Mark Hoyle - Tyco Healthcare. HUG Co-chair.**

# HUG - Yesterday, Today & Tomorrow...

The HUG is concentrating particularly on ensuring that appropriate data structures are selected in order to meet common business needs, and to help ensure data standardisation in healthcare.

If standardisation is applied globally, systems to help to improve patient safety will be developed and implemented quicker than if individual countries

were to pursue separate solutions. While the main focus at present is on a global solution for automatic product identification, to help to ensure the safety of patients worldwide, the HUG will be looking into other aspects of the healthcare supply chain (e.g. Data Synchronisation, electronic messaging and other systems).

**"There are pressing issues in healthcare today for which automatic identification - linear or two dimensional bar codes or radio frequency identification (RFID) - is part of the solution for dispensing errors, counterfeiting and diversion or fraud"**  
**Rich Hollander - Pfizer.**  
**HUG Co-chair.**



GS1 HUG™ in Brussels, 2005



GS1 HUG™ in Minneapolis, 2006



GS1 HUG™ in Paris, 2006

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# HUG Leadership Team

The **HUG Leadership Team** is responsible for the activities of the **HUG**. It comprises a minimum of 7 and a maximum of 12 full members. The seats are split by region; 5 North America, 5 Europe and 2 Asia/Japan region. The Leadership Team selects two Co-Chairs. Qualifications to serve as a Co-Chair include prior experience in the HUG Leadership Team. The Co-Chairs provide representation from all healthcare sectors and an attempt will be made to keep a geographical balance. The Leadership Team holds regularly conference calls to monitor progress, discuss issues and meet in person in connection with the HUG conferences, which are held in various geographical locations. Further face-to-face meetings are organised as required.

**Baxter**

**Johnson & Johnson**

**MERCK**

**Pfizer**

**PREMIER**

**B|BRAUN**  
SHARING EXPERTISE

**Medtronic**  
Alleviating Pain - Restoring Health - Extending Life

**Comparatio Health GmbH**

**tyco**  
Healthcare

## HUG Work Teams

The HUG Leadership Team initiates **Work Teams** to work on clearly define global requirements, with expertise provided by HUG members and, where necessary, support from GS1. Each Work Team works to a defined scope, objectives and deliverables. Since the formation of the HUG in May 2005, a number of Work Teams have already completed projects or the teams have been merged with other teams to work on enlarged requirements. Work Teams will continue to evolve, depending upon changing or new requirements.

Further details can be found at: [www.gs1.org/hug/work\\_teams/](http://www.gs1.org/hug/work_teams/)

## HUG Local/Regional Teams

In addition to the HUG Work Teams, sometimes it becomes advantageous to create **HUG Local/Regional Teams**. The teams work on clearly define local or regional requirements, with expertise provided by the HUG Work Teams, the local/regional GS1 member organisation and local HUG members. Each local/regional team works to a defined scope and deliverables. These deliverables could be to resolve a local requirement, implement a global requirement or turn a local requirement into a global standard. The teams are there to reduce global diversity and reduce potential complications for manufacturers or the supply chain. Currently the following local/regional teams are in operation and up-to-date information can be obtained from the HUG (Work Teams) or Member Organisation's website.

Further details can be found at: [www.gs1.org/hug/work\\_teams/local\\_hugs.html](http://www.gs1.org/hug/work_teams/local_hugs.html)

## HUG Support Teams

Within the HUG Leadership Team are two permanent **Support Teams - Membership and Communication**. These teams are lead by; Volker Zeinar, B.Braun & Jim Willmott, Smiths Medical.

The objective of the **Membership Support Team** is to organise HUG enlargement to progressively include all stakeholders: manufacturers, retailers, hospitals, pharmacy chains, distributors, regulatory bodies and health industry associations. Currently, technology and solution providers can only be involved by invitation.

The objective of the **Communication Support Team** is to lead and organise internal and external communications of the HUG and establish the HUG as the leading voice in the area of automatic data identification in the healthcare industry. This includes; Press Releases, Articles for Publication, Newsletters, Formal Communications, Structure & Content of the HUG website and support for the HUG Work Teams and HUG Local/Regional Teams. The Support Team works closely with the HUG Leadership Team and the GS1 Global Office.

Further details can be found at: [www.gs1.org/hug/work\\_teams/support\\_teams.html](http://www.gs1.org/hug/work_teams/support_teams.html)

# HUG Work Teams

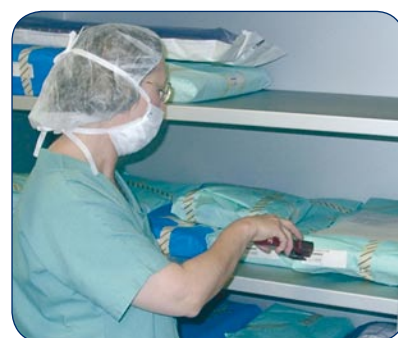
## • Business Case

**Scope:** International (global) coverage of all patients, regulatory bodies, supply chain participants. It includes healthcare providers as well as first and third party payers.

**Objectives:** Develop a compelling business case to demonstrate the benefits of using a GS1 global standard for automatic identification in healthcare. The case will be applicable to linear bar codes, 2D codes, and RFID. The case will be based on direct, first hand data gathered from the international environment.

**Deliverables:** A full report of the findings for printing and Internet publication. From the report, an executive summary will be prepared for top management and electronic presentation material for regulators and general audiences. The executive summary will include details of benefits that are important to high level management.

**Leaders:** Ed Dzwil - Johnson & Johnson  
Dr. Hugh Lockhart - MSU School of Packaging



## • Public Policy

**Scope:** International, National, Regional laws, regulations and directives regarding use of auto-identification in healthcare.

**Objectives:** Organise the industry around a single position to drive future standards and influence regulations around the world. Work with existing healthcare industry organisations, regulators and advocacy groups in delivering the position of the HUG. Identify regulatory, commercial, and process obstacles to implementing GS1 standards in the global healthcare sector. Develop strategies and solutions to overcome obstacles and speed adoption.

**Deliverables:** Maintain a global reference of applicable laws, regulations and standards. Provide guidance to HUG membership including governmental agencies and healthcare trade associations. Prepare specific responses to authorities regard public policy as it relates to auto-identification of healthcare products.

**Leaders:** Jackie Rae Elkin - Medtronic



**"If standardisation is applied globally, systems to improve patient safety will be developed and implemented quicker than if individual countries were to pursue separate solutions."**

**Rich Hollander - Pfizer.  
HUG Co-chair.**



# HUG Work Teams

## • Auto-ID Data

**Scope:** 1) From the moment a product is “finished” in manufacturing to the end of patient treatment. 2) Capture of data to be used for adverse event reporting. 3) Animal health products will be in the scope for gathering requirements only. 4) Food services will not be included other than therapeutic nutritional products. 5) Equipment used to transport patients is out of the scope, other than those classified as medical devices. 6) Facility assets used by a patient such as tables, lights, etc., is out of the scope.

**Objectives:** To improve patient safety by standardising the data content for healthcare applications of automatic identification data capture systems. The work team will generate the business and data requirements required for all products within the scope of the HUG.

**Deliverables:** A report defining the business and data requirements will be delivered to the HUG Leadership Team for HUG membership vote. This document will be used by the Serialisation, Data Carrier and AIDC Application Standards Work Teams for incorporation into the final AIDC Application Standard.

**Leaders:** Mark Walchak - Pfizer  
Mark Hoyle - Tyco Healthcare



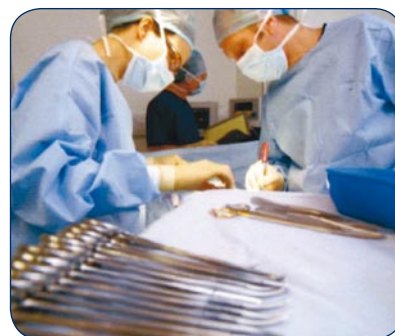
## • Serialisation

**Scope:** Define serialisation schema for healthcare products, with product traceability for patient safety as the highest priority (how and where to use mass serialisation for traceability). This will be from the point of manufacturing to the time of administration/patient treatment. In some cases reverse logistics will be taken into account. The scope will include: vaccines, biologics, therapeutic/nutritional products, pharmaceuticals and medical devices (e.g. instruments & implants).

**Objectives:** To review and document business and regulatory requirements for serialisation by; size (capacity needed), for example, size needed for: all healthcare by product (GS1 HUG™), by product (GTIN), or by lot, serial number, meaningful numbers versus randomisation & capacity effect, allocation decentralisation/centralisation & effect on capacity and structure.

**Deliverables:** A defined set of business/regulatory requirements covering serialisation schema. These requirements will be utilized by the Data Carrier and Auto-ID Data Work Teams.

**Leaders:** Steve Hess - Merck  
Massimiliano Molinari - Johnson & Johnson



## • Data Carrier



**Scope:** This Work Team will be established when the **Auto-ID Data** and **Serialisation** Work Teams have completed their deliverables, inline with the HUG Roadmap ([www.gs1.org/hug/about/roadmap.html](http://www.gs1.org/hug/about/roadmap.html)).

**Objectives:** Identify the data carriers for healthcare product packaging and direct marking. Establish standards for carrier printing/marking/encoding, scanning/verifying/decoding and quality (where and when to use which bar code type: e.g. EAN/UPC, GS1-128, GS1 DataMatrix, GS1 DataBar™ [RSS] or RFID tags).

**Deliverables:** To define global data carriers.

**Leaders:** To be determined.



# HUG Local/Regional Teams

- Australasia



[www.gs1au.org/home.asp](http://www.gs1au.org/home.asp)



[www.gs1nz.org/](http://www.gs1nz.org/)



- Canada



[www.gs1ca.org/home.asp](http://www.gs1ca.org/home.asp)



- Chile



[www.gs1chile.org/default.asp](http://www.gs1chile.org/default.asp)



- France



[www.gs1.fr/gs1\\_fr/secteurs\\_d\\_activite\\_\\_1/sante](http://www.gs1.fr/gs1_fr/secteurs_d_activite__1/sante)



- Germany



[www.gs1-germany.de](http://www.gs1-germany.de)

- Serbia & Montenegro and Macedonia



[www.gs1yu.org/](http://www.gs1yu.org/)



[www.mchamber.org.mk/](http://www.mchamber.org.mk/)



- Switzerland



[www.gs1.ch/](http://www.gs1.ch/)

More to follow ...

[www.gs1.org/hug/work\\_teams/local\\_hugs.html](http://www.gs1.org/hug/work_teams/local_hugs.html)

# Join the HUG - Global Healthcare User Group



For more information or to join the HUG, contact Ulrike Kreysa at [ulrike.kreysa@gs1.org](mailto:ulrike.kreysa@gs1.org) or contact your local GS1 Member Organisation.  
The GS1 Member Organisations list is available at: [www.gs1.org/contact/worldwide.php](http://www.gs1.org/contact/worldwide.php)

Members of the HUG should:

- have a global position in their company
- have the agreement of their management for their engagement
- be actively involved and participate in the work of the HUG
- be able to represent the strategy, opinion and experience of their company regarding product identification and e-commerce in the supply chain
- be business process orientated experts who are well-connected within their organisation
- be familiar with GS1 Standards or at least have an overview about GS1 Standards
- be able to promote the developed global standards throughout their organisation



[www.gs1.org/hug/](http://www.gs1.org/hug/)

**"The organisation of the HUG, the engagement of the members and their willingness to share expertise are the key success factors. Patient safety is a valuable matter which has to be protected and improved. The GS1 HUG™ wants to contribute with voluntary global standards." Volker Zeinar - B.Braun. Former HUG Co-chair.**

**"The HUG was formed to develop global standards for the healthcare industry when it comes to automatic identification and act as the leading voice for the healthcare industry. Many of the standards required already exist, but there are a multitude to choose from. The HUG is developing global healthcare application standards relying on the GS1 system." Rich Hollander - Pfizer. HUG Co-chair.**



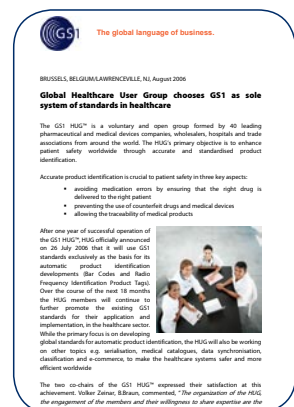
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The PDF version of this brochure has hyperlinks to associated websites.  
To ensure that you have the current version please visit [www.gs1.org/hug/](http://www.gs1.org/hug/)

# GS1 - The global language of business

## GS1 HUG™ - Global Healthcare User Group



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