

Why GS1 Healthcare?

The mission of GS1 Healthcare is **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.

What is GS1 Healthcare?

GS1 Healthcare is a voluntary, global user community bringing together all healthcare stakeholders: pharmaceutical and medical devices manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies and associations.

The global Healthcare user group wants to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

The global Healthcare user group is implementing the Roadmap towards global supply chain standards as agreed by the community. GS1 facilitates the global standards development process.

Local Healthcare user groups have also been established in a number of countries around the world. These groups ensure that specific local requirements are taken into account in the global standards and promote and support local adoption and implementation of such standards.

What is new?

In the last few years, two GS1 user communities were working in parallel on global standards, each from their own perspective:

- EPCglobal Healthcare & Life Science Industry Action Group (HLS)
- GS1 global Healthcare User Group (GS1 HUG™)

Recognising the commonality between the objectives of both groups, the leadership team of both groups agreed to join forces in the development and implementation of global standards. This will make the standards development process for healthcare standards more efficient. It also means a single group for all stakeholders to be engaged with.

What have the user groups achieved so far?

Development of global standards:

HLS and HUG have both been working according their agreed Roadmap. Several milestones have already been achieved by the previous user groups, including the:

- ratification of the Healthcare GTIN Allocation Rules Standard
- definitions for which data is needed when marking medical products
- serialisation: serial & lot number size and capacity identifier
- ratification of the Pedigree Messaging Standard

Promotion of global standards:

Both user groups, together with GS1 and the respective GS1 Member Organisations in that country, have also been successful in promoting the adoption of global standards in healthcare towards regulatory bodies. A few examples:

- The user group is working with the Global Harmonisation Task Force (currently chaired by the US FDA) for Unique Device Identification (UDI),.
- The user group is closely working together with the California Board of Pharmacy in order to have GS1 and GS1 EPCglobal Standards enabling stakeholders to comply with e-Pedigree legislation.
- The Department of Health (UK) chose the GS1 Standards for implementation in public hospitals in England.
- The Council of Europe's Expert Group on Safe Medication Practices makes a strong recommendation to European Healthcare organisations to update the national and European legislative framework to require unit-of-use marking based on GS1 Standards.
- The Ministry of Health in New Zealand approved a Medication Safety Project based on GS1 Standards.
- Australia NEHTA endorsed the adoption of global standards in healthcare.
- Shanghai regulated a traceability system for implantable medical devices based on GS1 Standards.

In general, the user group is in close contact with a large number of regulatory bodies advocating the benefits to everyone of global standards: Australia, Canada, France, Germany, Japan, Korea, Italy, Spain, UK, US, etc.

GS1 and both user groups have also been working with a number of other stakeholders to promote global standards. A few examples:

- EUCOMED recommends GS1 Standards to its members.
- The purchasing network of university hospitals in France has endorsed GS1 Standards.
- The U.S. Healthcare Supply Chain Standards Coalition (HSCSC) is calling for industry-wide adoption of organisational and product identifiers from GS1.

What will the future bring?

GS1 Healthcare aims to continue and enlarge its activities.

Development of global standards:

A common GS1 Healthcare Roadmap for the Global Standards development process will be agreed. The current draft version includes 3 main work streams:

- AIDC Application Standards
- Global Traceability Solution

- Data Synchronisation and Product Classification

Promotion of global standards:

GS1 and GS1 Healthcare will continue to work with regulatory bodies and all other stakeholders advocating the benefits of global standards for everyone.

Why should I join?

Joining the global Healthcare user group allows you to:

- voice your requirements in the standards development process
- be involved in the promotion of global standards towards all stakeholders, including regulatory bodies
- remain informed about the evolution of automatic identification regulations and standardisation in Healthcare around the world

A large number of leading companies and institutions have been active in this user community and we welcome anyone to join and work towards a safer and more efficient Healthcare supply chain. See www.gs1.org/healthcare for a list of members.

How can I join?

The global Healthcare user group of GS1 Healthcare welcomes the following stakeholders as voting members: pharmaceutical or medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, and logistics providers.

Regulatory bodies, associations and educational institutes are welcome as non-voting members.

To join the global Healthcare user group, please contact ulrike.kreysa@gs1.org

To join a local Healthcare user group, please contact your local GS1 Member Organisation. For contact details, please check <http://www.gs1.org/contact/worldwide.php>.

What will it cost?

To participate in GS1 Healthcare global standards development activities, all companies must pay an annual membership fee which is set by GS1 in coordination with the GS1 Healthcare Leadership Team. For more information, please contact ulrike.kreysa@gs1.org or your local GS1 Member Organisation.

GS1 is not-for-profit organisation and the funds collected are only to cover the costs of the GS1 Healthcare activities, in particular facilitating the global standards development process according to the agreed Roadmap. This covers the full range of GS1 Standards: identification keys, bar codes, EPC/RFID, GDSN, and e-COM.

To use GS1 identification numbers, a company needs to become a member of (a) local GS1 Member Organisation(s) who allocate(s) a company prefix to them. This company prefix allows that member to create and use identification numbers for products (GTIN), locations (GLN), etc. The GS1 System ensures that these numbers are unique all over the world.

GS1 Member Organisations also provide support and training for any GS1 standards (bar codes, EPCglobal/RFID, data synchronization and product classification, and eCom). Although GS1 identification numbers can be used in any country, it is also valuable for internationally active members to become member of GS1 Member Organisations outside the country/countries allocating a company prefix. Local GS1 Member Organisations provide support and local expertise to promote and implement GS1 Standards in that country. They also gather local requirements and promote them to be taken into account in the global standards development.

GS1 has 108 local Member Organisations. Membership fees vary per country and depend on the services required.

How is GS1 Healthcare organised?

The global Healthcare user group of GS1 Healthcare consists of:

- All members, voting and non-voting
- A Leadership Team with members balanced across geographies, from the healthcare supply chain and industry.
 - o The Leadership Team develops and maintains the overall GS1 healthcare strategy, and manages daily operations.
 - o The Leadership Team represents GS1 Healthcare to external groups and organisations.
 - o Their Co-Chairs preside at Conferences and Meetings and facilitate the consensus process
- Work Teams
 - o The Leadership Team creates Work Teams to respond to, or drive specific initiatives. These Work Teams are open to all members.
 - o Work Teams discuss and agree on business requirements for global standards.
 - o Current Work Teams include AIDC Application Standards, Carrier, Traceability in Healthcare, and Data Synchronisation & Product Classification. Others to be considered.
 - o Work Teams that have already completed their work include GTIN Allocation Rules, AIDC Data Requirements and Serialisation.

The Leadership Team and the Work Teams meet regularly via conference call and three times per year physically in carefully chosen locations. To ensure continuation in the process, members are expected to attend regularly, or send representatives.

GS1 Member Organisations are also represented in the Leadership Team and Work Teams, without voting rights. They represent local stakeholders and voice their local needs in the global decision process.

The GS1 Global Office facilitates and supports all of the above activities.

What are local Healthcare user groups?

A GS1 local Healthcare user group brings together the full range of local healthcare stakeholders including healthcare providers, pharmacies, industry associations, group purchasing organizations, manufacturers, distributors, and technology and solution providers. Local Healthcare user groups focus on the adoption and implementation of global standards in the Healthcare supply chain. This includes the development of tools and resources for use by the healthcare industry, including standards implementation guidelines, case studies of successful applications, as well as training and education. The user group will also ensure that local requirements are taken into account when the global Healthcare user group is developing global standards.

How does the GS1 standards development process work?

GS1 Healthcare Work Teams define use cases and business requirements.

Once defined, these use cases and business requirements go into:

- GSMP (Global Standards Management Process) Work Groups: e.g. identification keys, bar codes, data synchronisation and product classification
For more information about GSMP, please refer to www.gs1.org/services/gsm/overview/index.html
- EPCglobal JRG (Joint Requirements Groups) and Technical Work Groups: e.g. EPC, RFID and EPCIS
For more information about the EPCglobal process, please refer to www.epcglobalinc.org/standards/sdp/

These Work Groups define technical requirements and develop standards.

I am an Industry Association, does anything change for me?

No, associations are a very important partner in the standards development process and in the adoption and implementation of such standards. So far, associations have been closely involved in the activities of both HLS and HUG. The GS1 Healthcare Governance Charter foresees that “*organisations with a keen interest in standards development and patient safety*” can become non-voting member and are encouraged to participate in work teams and events.

I am a Technology or Solution Provider, how can I be involved?

Technology and Solution Providers can participate in the definition of technical requirements and the development of standards by becoming engaged in GSMP Work Groups or EPCglobal JRG or Technical Work Groups.

The GS1 Healthcare Work Teams consist of end users (see standards development process), but may invite Technology and Solution Providers as needed.

Technology and Solution Providers can attend the plenary sessions of GS1 Healthcare Conferences.