



The Global Language of Business

# GS1 Healthcare US

## GS1 Healthcare US<sup>®</sup> Initiative Charter

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## About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

## About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

## About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

## About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.



## 1 GS1 Healthcare US Initiative

GS1 Healthcare US<sup>®</sup> is an industry group that is driving forward open, global standards to help healthcare companies improve the accuracy, speed, and efficiency of the supply chain and delivery of patient care.

Through the collaboration and cooperation of companies and organizations throughout the U.S. healthcare supply chain, GS1 Healthcare US is making it possible for healthcare to move toward adopting GS1 Standards for identifying, capturing, and sharing data as the foundation for improved business and care delivery processes.

GS1 Healthcare US Initiative members provide technical and functional expertise to address major industry issues through the adoption and use of GS1 Standards. The initiative's Workgroups bring targeted teams together to develop a variety of implementation guidance and tools, educational materials, and industry recommendations in support of the Initiative.

By participating, you can take an active role in driving positive change and innovation in your industry. Choose what topic areas are of particular interest and importance to your organization:

- Safer patient care
- Operational efficiencies
- Supporting regulatory requirements for U.S. Food and Drug Administration (FDA) Unique Device Identification or UDI and the Drug Supply Chain Security Act (DSCSA)

All members of the GS1 Healthcare US Initiative are encouraged to participate in our workgroups and may join at any time.

## 2 Vision

Establish GS1 Healthcare US as the open and neutral source for manufacturers, distributors, providers, dispenser pharmacies, group purchasing organizations, regulatory agencies, trade organizations, and other similar stakeholders seeking input and direction for global standards in healthcare for patient safety, supply chain security and efficiency, traceability and accurate data synchronization in the United States (U.S.).

## 3 Mission

Our mission is to proactively work with healthcare leaders to adopt and effectively utilize GS1 Standards, best practices, and standards-based solutions to improve patient safety, supply chain security and efficiency.

## 4 Objectives

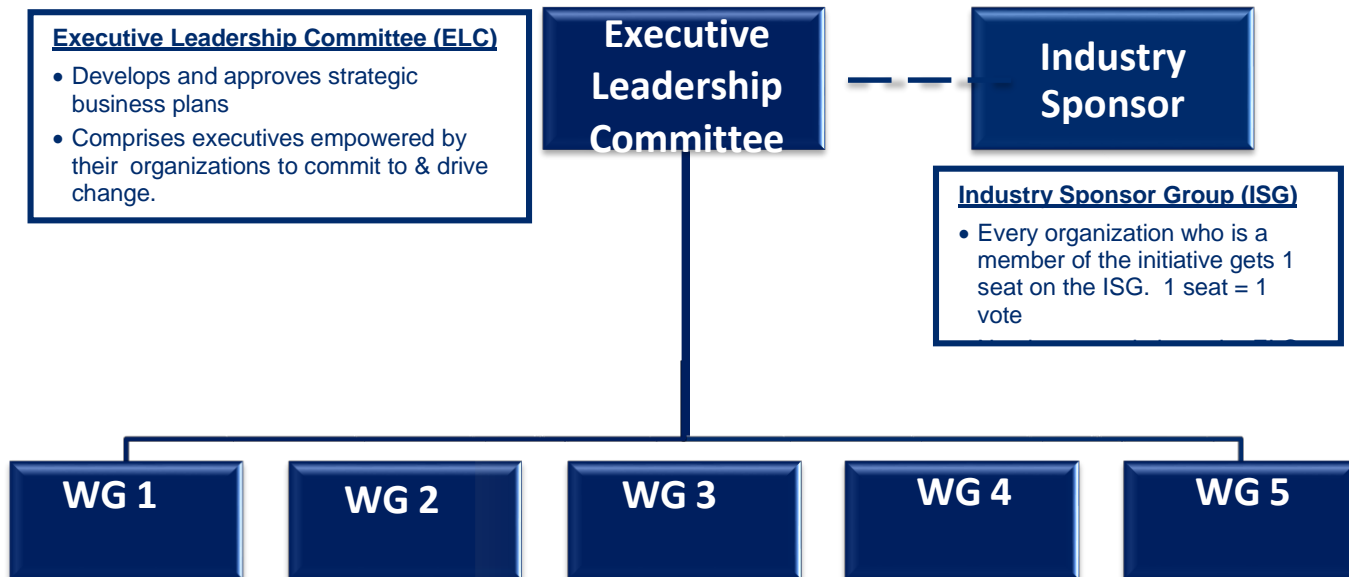
- Work with key partners in the U.S. healthcare supply chain to develop an understanding of the potential of globally unique product identification, automatic data capture, traceability, and electronic messaging and data synchronization.
- Develop and deploy a common approach and use of the GS1 System to achieve efficiency in U.S. healthcare and adjacent supply chain operations.
- Develop documentation based on the GS1 System and promote awareness of the GS1 Healthcare US implementation guidelines.
- Gather and support U.S.-specific user requirements for submission to GS1 Healthcare (Global) team. Review global standards and guidelines in development and comment as appropriate.
- Study, adapt, and adopt all other guidelines developed by GS1 Healthcare (Global), as appropriate.
- Foster and support implementation of the principles of traceability using the GS1 System in the U.S. healthcare and adjacent supply chains, combining product, asset, and location identification and electronic messaging to enable full traceability from the manufacturer to the patient / end user to disposal.
- Actively foster and support awareness of the GS1 System in the U.S. in alignment with the global objectives of the GS1 System.
- Support U.S. implementation initiatives and create case studies to demonstrate the benefit of using the GS1 System to stakeholders.
- Encourage and demonstrate best practice implementation of the GS1 System in the U.S.
- Facilitate awareness and understanding of the entire GS1 product and service portfolio, including GS1 identification numbers, GS1 barcode symbols, United Nations Standard Products and Services Code® (UNSPSC®), GS1 Global Product Classification (GPC), electronic messages, Global Data Synchronization Network™ (GDSN®) and Electronic Product Code (EPC®)-enabled RFID (EPC/RFID).

## 5 Accountability

GS1 Healthcare US is accountable to the GS1 US Board of Governors, GS1 US Industry Committee, GS1 US Senior Leadership Team, and GS1 US members.

## 6 Initiative Structure & Governance

### 6.1 Membership Structure



### 6.2 Executive Leadership Committee

The GS1 Healthcare US Initiative is governed by the GS1 Healthcare US Executive Leadership Committee (ELC). The ELC is composed of executives empowered by their organizations to commit to and drive change.

The GS1 Healthcare US Executive Leadership Committee is elected to represent the participating industries in the healthcare space: 4 healthcare providers, 2 distributors/wholesalers, 3 medical device manufacturers, 3 pharmaceutical/biologic manufacturers, 3 solution providers, 2 group purchasing organizations, 2 dispensers/pharmacies, 3 associations and GS1 US. The ELC is governed by the *GS1 Healthcare US Charter*. The Executive Leadership Committee manages the initiative and develops and approves strategic and tactical business plans, monitors progress and results, as well as resolves issues and/or barriers to success. The ELC is responsible for working with the general GS1 Healthcare US membership to:

- Develop and drive the overall GS1 Healthcare US strategy and work plans.
- Represent GS1 Healthcare US to external healthcare-related groups and organizations.

The Executive Leadership Committee may elect ad hoc members to further the objectives of the initiative. These ad hoc members will participate in the Executive Leadership Committee but cannot vote. The members will serve up to a one-year term. The terms can be renewed by the ELC. These ad hoc members serve at the discretion of the ELC.

### 6.2.1 Election Process

- Candidate Requirements
  - Executive Leadership Committee candidates can be nominated from any GS1 Healthcare US member organization, including self-nominations, for each healthcare category.
  - Executive Leadership Committee members must be engaged in GS1 Standards implementation efforts and hold a position of influence within their organization regarding the promotion, adoption and implementation of the developed global standards and best practices.
  - Executive Leadership Committee candidates must be actively working in the category they are running for.
- Executive Leadership Committee members are elected following the process documented below:
  - Half of the Executive Leadership Committee, comprising at least one (1) member from each healthcare category, is slated for election each year in the fourth quarter.
  - A voting ballot is created and each GS1 Healthcare US Industry Sponsors Group member votes [one (1) vote per organization] on the candidates for each healthcare category.
  - The candidates with the most votes in each category are elected to the Executive Leadership Committee for a two-year term (with the exception of Ad Hoc members who serve a one-year term as noted above)). The term begins in January and ends in December of the following year.
  - When positions for a category are filled in the same year, the candidate(s) with the highest number of votes will serve two years and the candidate(s) with the next highest votes will serve one year.
  - Should the number of nominations equal the number of open positions in any given category, those nominated candidates will be automatically appointed and no vote will be conducted for that category

### 6.2.2 Responsibilities

- Executive Leadership Committee members must attend at least sixty-six percent (66%) of the Executive Leadership Committee meetings. Members who do not meet this criterion are subject to removal from the Executive Leadership Committee. (NOTE: The Executive Leadership Committee position is filled by the person voted into the position by the company's category. Consequently, only the person voted into the position can participate in Executive Leadership Committee activities. Substitutes are not permitted.)
- Approve new workgroups and their associated charters as well as the elimination of any workgroups.
- Approve major changes to existing workgroup work plans. The proposed changes to existing workgroup work plans will be presented by the workgroup chair(s) to the Executive Leadership Committee for review and approval. Presentations to the Executive Leadership Committee should include a summary of the issue, why it necessitates a modification of an existing work plan or is outside the scope of existing workgroups, the expected timeline for resolution, and deliverables.
- At the beginning of each calendar year, the Executive Leadership Committee will review and approve a strategic plan as well as approve the workgroup work plans for the year. These plans will be in alignment with the GS1 Global Healthcare strategy and roadmap, as appropriate.
- Review and approve all changes to this GS1 Healthcare US Charter.
- Executive Leadership Committee members will work with the GS1 Healthcare US membership to:



- Develop and drive the overall GS1 Healthcare US strategy and work plan.
- Assist in managing: meeting planning, public relations, membership and policy.
- Ensure supply chain stakeholder balance in the GS1 Healthcare US membership, the Executive Leadership Committee, and workgroups as applicable.
- Provide input in GS1 Healthcare US positions in response to regulatory, customer and local Standards initiatives.
- Represent GS1 Healthcare US to external healthcare-related groups and organizations.
- Represent the views and work outputs of GS1 Healthcare US to the GS1 US Board of Governors, GS1 US Senior Executive Leadership Committee, and GS1 Healthcare.
- Ensure participation in GS1 Healthcare standards development.
- Where appropriate, represent GS1 Healthcare US by attending conferences.
- Represent their industry category, or designate an appropriate delegate from their organization, in workgroup meetings by physical presence or teleconference.
- Convene and preside over GS1 Healthcare US meetings and teleconferences.
- Facilitate the voting process within GS1 Healthcare US.

### 6.2.3 Term

- The Executive Leadership Committee members will serve a two-year term, which is renewable through the annual Executive Leadership Committee voting process.
- In the event an Executive Leadership Committee member changes employment to an organization that is not a GS1 Healthcare US member during a serving term, the member automatically resigns from the ELC position. The Executive Leadership Committee will decide whether to hold a special election following the election process or wait for the annual election to fill the position.
- In the event an Executive Leadership Committee member changes employment to an organization that is a GS1 Healthcare US member and is not in the same healthcare category during a serving term, the Executive Leadership Committee will decide whether to allow the member to serve to the end of the subject year, hold a special election following the election process or wait for the annual election to fill the position.
- In the event an Executive Leadership Committee member changes employment to an organization that is a GS1 Healthcare US member and is in the same healthcare category during a serving term, the member will complete their elected term.

### 6.3 Industry Sponsors Group

The GS1 Healthcare US Industry Sponsors Group (ISG) is comprised of one primary contact for each member organization. Each member organization receives one seat on this group. The ISG elects the ELC.

- Membership is open to all organizations in healthcare and adjacent sectors including, but not limited to: healthcare providers, dispensers/pharmacies, distributors /wholesalers, pharmaceutical manufacturers, medical device manufacturers, biological product manufacturers, group purchasing organizations, government users, industry associations, government regulatory agencies /authorities, solution providers (software, hardware and consultants), and educational institutions. At any time, representatives of government regulatory agencies / authorities may be invited to share experiences and information with GS1 Healthcare US participants.
- Participation in GS1 Healthcare US is voluntary.

- Membership in GS1 Healthcare US requires organizations to satisfy the financial commitments described in Section 10, as applicable.
- All member organizations of GS1 Healthcare US have one seat and one vote on the Industry Sponsor Group.
- Member Organization Participation
  - All employees/representatives of GS1 Healthcare US member organizations are encouraged to participate in workgroups and attend GS1 Healthcare US events.
  - Employees/representatives of GS1 Healthcare US member organizations are eligible for election to the ELC.
- Voting Rules
  - Each member organization has only one (1) vote. Member organizations should keep GS1 US apprised of the current contact information for their designated voting member.
  - Decisions will be reached by majority vote. However, a voting member or GS1 US facilitator may request a vote on a resolution.
  - Resolutions will be decided by simple majority and a quorum of 66% of the voting members is necessary. Voting shall be by voice, show of hands, or ballot.

## 6.4 Workgroups

[\*GS1 Healthcare US Initiative workgroups\*](#) are user-driven industry groups that organize members based on defined business challenges and opportunities to explore solutions, create adoption plans, and foster broad collaboration for the adoption and use of GS1 Standards in the healthcare industry. Workgroups bring targeted teams together to develop a variety of implementation tools, educational materials, and industry recommendations in support of the Initiative.

## 6.5 Open Industry Topic Webinars

The GS1 Healthcare US team will host open industry topic webinars throughout the year. These webinars provide an opportunity to interact with the greater healthcare industry regarding the work accomplished within GS1 Healthcare US. These events may be used to inform, educate, influence, and/or elicit feedback from companies who are and are not members of GS1 Healthcare US.

## 6.6 Role of GS1 US

- Support GS1 Healthcare US objectives.
- Facilitate and support the Executive Leadership Committee and the workgroups.
- Provide GS1 Healthcare US with current and relevant information about the work areas and outputs.
- Provide relevant communication to GS1 Healthcare US.
- Ensure GS1 Healthcare US has sufficient support from GS1 US.
- Drive alignment of GS1 Healthcare US goals and objectives with those of GS1 Healthcare.
- Ensure all of GS1 US is familiar with the work of GS1 Healthcare US.
- Ensure all work is aligned with other initiatives within GS1 US.
- Ensure every workgroup meeting adheres to the code of conduct and antitrust of GS1 US, which at a minimum is a reading of the Antitrust and Code of Conduct at the beginning of every meeting.

## 7 Meetings

### 7.1 Frequency

- Executive Leadership Committee - There will be at least four teleconference and two face-to-face meetings per year, with the locations and dates set at the end of each calendar year for the coming year by the Executive Leadership Committee.
- Workgroups – Meeting frequency will be determined by the GS1 US facilitator and industry workgroup chair(s).

### 7.2 Antitrust and Code of Conduct

Every GS1 Healthcare US meeting shall have a GS1 US participant to enforce the GS1 US antitrust and code of conduct guidelines. Unless there is a GS1 US employee at the meeting, the meeting is not an official GS1 US meeting.

### 7.3 Minutes

GS1 Healthcare US shall have minutes for the Executive Leadership Committee. These minutes at a minimum will include an antitrust statement, a code of conduct statement, an agenda, the attendees and the applicable decisions or actions. These minutes will be available for review prior to the next scheduled ELC meeting.

## 8 Document Development Process

All outputs of GS1 Healthcare US workgroups and Executive Leadership Committee including documents, position papers, education materials, and responses to public policy must be approved by the Executive Leadership Committee before these outputs are made publicly available. Publicly available means it is shared broadly with the healthcare community such as posting to the GS1 Healthcare US website.

## 9 Communications

### 9.1 Representing GS1 Healthcare US

- Communications on behalf of GS1 Healthcare US with third parties will be undertaken by GS1 Healthcare US Executive Leadership Committee members in conjunction with GS1 US.
- For presentations to third parties, a standard GS1 Healthcare US PowerPoint template will be used. The presentation shall be converted to a PDF document for distribution and/or download.

### 9.2 Website and Community Room

- The GS1 Healthcare US website and community room will be maintained by GS1 US.
- The community room will be updated following each meeting with information relating to the meeting including agendas, meeting minutes, presentations, work outputs, and the work plan.

## 10 Financials

GS1 Healthcare US is a self-funded initiative. GS1 Healthcare US fees will be based on expenses necessary to sustain operations, publication, public relations of the group, and other appropriate costs.

Our standard annual membership fee is \$4000 for most types of companies. If your company is a hospital, healthcare provider, academic institution or association, a government agency, or a standards organization, you may qualify for a lower annual fee. Refer to the fee chart below for specifics:

Membership Type	Annual Fee
Industry Initiative Membership	\$4,000
Hospital / Healthcare Provider	\$500*
Academic Institution / Association / Government Agency / Standards Organization	No charge*

\*Verification of eligibility may be required

- Industry associations, government regulatory agencies/authorities, and educational institutions are exempt from membership fees.
- The Annual Fee is by company. There is not a limit to the number of individuals from the member company that can be involved in initiative programs.
- Conference fees will be charged to cover cost.
- Payment of GS1 Healthcare US membership fees are separate and distinct from all other GS1 US fees, such as a GS1 Company Prefix License and GS1 US DataHub® Subscriptions.

## 11 Revision History

Release #	Approval Date	Change(s)
1.0	May 22, 2008	First version issues
1.1	December 10, 2010	Section 6.1: Added two Solution Provider, non-voting positions to the GS1 Healthcare US Executive Leadership Committee  Section 9.1.1: Changed the minimum number of face-to-face meetings from three (3) to two (2) per year.
1.2	October 7, 2010	Created Addendum (section 14): Changes in Workgroup Plans and the Creation of Additional Workgroups.
1.3	October 22, 2010	Revised Section 6, including the following additions: Sections 6.1.1.1.2, 6.1.1.5, 6.1.2.6, 6.3.1, 6.4.2, and 6.4.3.
1.4	November 1, 2012	Revised Section(s) 5.1.4, 6.1.1.1, and Section 13.
1.5	December 6, 2012	Revised Section 13.2
2.0	March 20, 2013	Second version issued
3.0	February 2, 2015	Aligning for the new ELC organization
4.0	January 4, 2023	Updated to reflect current workgroups and processes

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## Improvements

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\*If applicable

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