



GS1 HEALTHCARE US

GS1 Healthcare US Charter

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THE GLOBAL LANGUAGE
OF BUSINESS

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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 the global information standards organization GS1, brings industry communities together to solve supply-chain problems through the adoption and implementation of GS1 Standards. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, security and sustainability of their business processes. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-enabled RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). www.GS1US.org.

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 & 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 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 VISION

- 1.1 Establish GS1 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.).

* DSCSA, Section 581, definitions

2 MISSION

- 2.1 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.

3 OBJECTIVES

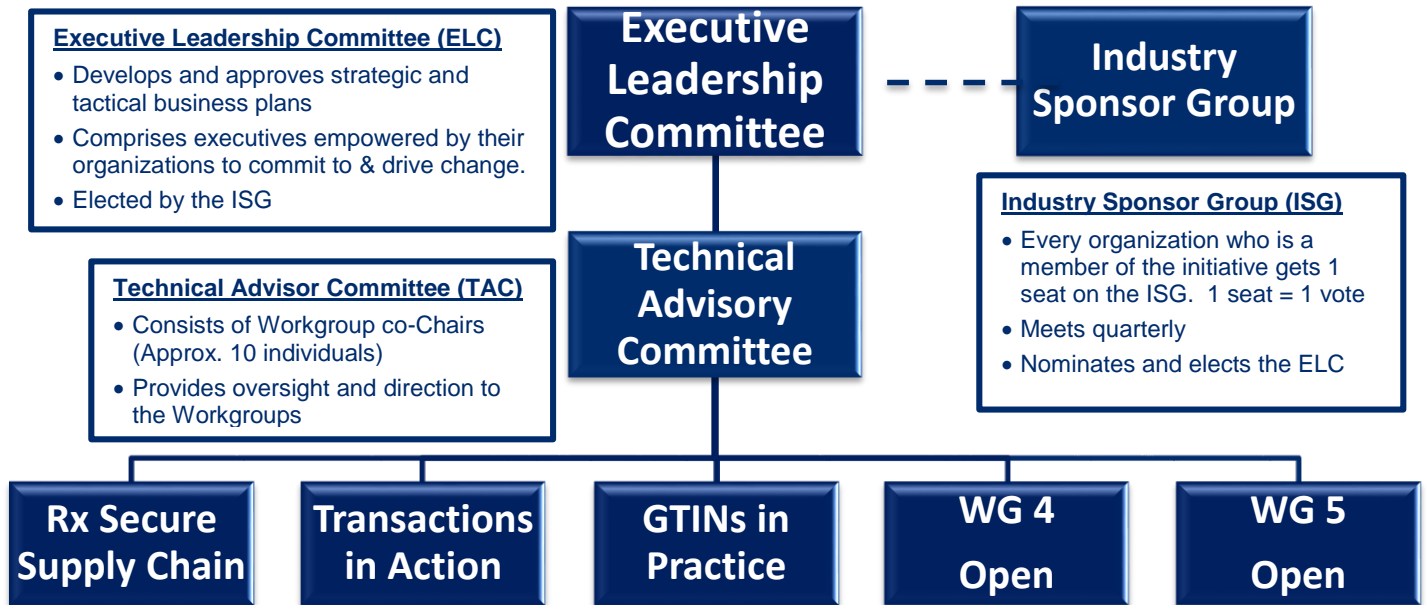
- 3.1 Work with key partners in the U.S. healthcare supply chain to develop an understanding of the progress of product identification, automatic data capture, traceability, and electronic messaging and data synchronization.
- 3.2 Develop a common approach and use of the GS1 System to achieve efficiency in U.S. healthcare and adjacent supply chain operations.
- 3.3 Develop documentation based on the GS1 System, and promote awareness of the GS1 Healthcare US[®] implementation guidelines.
- 3.4 Gather U.S.-specific user requirements and submit requirements to GS1 Healthcare (Global) team. Review global standards and guidelines in process and comment as appropriate.
- 3.5 Study, adapt and adopt all other guidelines developed by GS1 Healthcare as appropriate.
- 3.6 Foster 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.
- 3.7 Actively foster awareness of the GS1 System in the U.S. in alignment with the global objectives of the GS1 System.
- 3.8 Support U.S. implementation initiatives and create case studies to demonstrate the benefit of using the GS1 System to stakeholders.
- 3.9 Encourage best practice implementation of the GS1 System in the U.S.
- 3.10 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).

4 ACCOUNTABILITY

- 4.1 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.

5 MEMBERSHIP

5.1 Initiative structure



5.2 Industry Sponsor Group (ISG) Membership

- 5.2.1 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.
- 5.2.2 Participation in GS1 Healthcare US is voluntary.
- 5.2.3 Membership in GS1 Healthcare US requires organizations to satisfy the financial commitments described in Section 13, as applicable.
- 5.2.4 All member organizations of GS1 Healthcare US have one seat and one vote on the Industry Sponsor Group.

5.3 Member Organization Participation

- 5.3.1 All employees/representatives of GS1 Healthcare US member organizations are encouraged to participate in Workgroups and attend GS1 Healthcare US events.
- 5.3.2 Employees/representatives of GS1 Healthcare US member organizations are eligible for election to the ELC or TAC.

5.4 Voting Rules

- 5.4.1 Each member organization has only one (1) vote.
- 5.4.2 Decisions will be reached by majority vote. However, a voting member or GS1 US facilitator may request a vote on a resolution.
- 5.4.3 Resolutions will be decided by simple majority and a quorum of 50% of the voting members is necessary. Voting shall be by voice, show of hands, or ballot.

6 EXECUTIVE LEADERSHIP COMMITTEE

6.1 Composition

- 6.1.1 The GS1 Healthcare US Industry Sponsor Group members shall elect an Executive Leadership Committee through a nomination and voting process.
- 6.1.2 The composition of the ELC voting members is:
 - 4 healthcare providers
 - 2 distributors/wholesalers
 - 3 medical device manufacturers
 - 3 pharmaceutical/biologic manufacturers
 - 3 solution providers
 - 2 group purchasing organizations
 - 2 dispensers/pharmacies
- 6.1.3 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.
- 6.1.4 Two co-chairs may be elected at the first face-to-face Executive Leadership Committee meeting. The co-chairs serve a one year term and shall be from different voting categories. The role of the co-chairs will be to lead the meetings and initiative.

6.2 Election Process

6.2.1 Candidate Requirements

- 6.2.1.1 Executive Leadership Committee candidates can be nominated from any GS1 Healthcare US member organization, including self-nominations, for each healthcare category.
- 6.2.1.2 Executive Leadership Committee members must be engaged in GS1 Standards implementation efforts and be able to promote the implementation of the developed global standards and best practices in their organization.
- 6.2.1.3 Executive Leadership Committee candidates must be actively working in the category they are running for.

6.2.2 Executive Leadership Committee members are elected following the process documented below:

- 6.2.2.1 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.
- 6.2.2.2 A voting ballot is created and each GS1 Healthcare US Industry Sponsor Group member votes [one (1) vote per organization] on the candidates for each healthcare category.
- 6.2.2.3 The candidates with the most votes in each category are elected to the Executive Leadership Committee for a two-year term (note exception in 6.1.3). The term begins in January and ends in December of the next year.
- 6.2.2.4 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.

6.3 Responsibilities

- 6.3.1 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.)
- 6.3.2 Approve new Workgroups and their associated charters and the elimination of any Workgroups.
- 6.3.3 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.

- 6.3.4 At the beginning of each calendar year, the Executive Leadership Committee will review and approve a strategic plan as well as approving the Workgroup work plans for the year. These plans will be in alignment with the GS1 Global Healthcare roadmap, as appropriate.
- 6.3.5 Review and approve all changes to this GS1 Healthcare US Charter.
- 6.3.6 Executive Leadership Committee members will work with the GS1 Healthcare US membership to:
 - 6.3.6.1 Develop and drive the overall GS1 Healthcare US strategy and work plan.
 - 6.3.6.2 Assist in managing: meeting planning, public relations, membership and policy.
 - 6.3.6.3 Ensure supply chain stakeholder balance in the GS1 Healthcare US membership, the Executive Leadership Committee, and Workgroups as applicable.
 - 6.3.6.4 Provide input in GS1 Healthcare US positions in response to regulatory, customer and local Standards initiatives.
 - 6.3.6.5 Represent GS1 Healthcare US to external healthcare-related groups and organizations.
 - 6.3.6.6 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.
 - 6.3.6.7 Ensure participation in GS1 Healthcare standards development.
 - 6.3.6.8 Where appropriate, represent GS1 Healthcare US by attending conferences and Workgroup Meetings by physical presence or teleconference.
 - 6.3.6.9 Convene and preside over GS1 Healthcare US meetings and teleconferences.
 - 6.3.6.10 Facilitate the voting process within GS1 Healthcare US.
- 6.4 Term
 - 6.4.1 The Executive Leadership Committee members will serve a two-year term, which is renewable through the annual Executive Leadership Committee voting process (note exception in 6.1.3).
 - 6.4.2 In the event that 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 position. The Executive Leadership Committee will decide whether to hold a special election following the election process in Section 6.2 or wait for the annual election to fill the position.
 - 6.4.3 In the event that 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 in Section 6.2, or wait for the annual election to fill the position.

- 6.4.4 In the event that 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.

7 WORKGROUPS

- 7.1 The work of GS1 Healthcare US will be undertaken by Workgroups with defined charters and work plans.
- 7.2 Workgroup Chairs
- 7.2.1 In the fourth quarter of each year, the members of the Workgroup will elect Chair(s) by voting as outlined in Section 5.4. Replacement Chairs may be selected at any time as needed.
- 7.2.2 The Chair(s) of a Workgroup is/are responsible for:
- 7.2.2.1 Workgroup progress, according to its scope and deliverables.
- 7.2.2.2 Administration of the Workgroup.
- 7.3 Workgroup Outputs
- 7.3.1 Workgroup outputs that will be made publically available must be approved by voting as outlined in Section 5.4 by the Workgroup. Then these outputs will be presented to the Technical Advisory Committee.
- 7.3.2 At the end of each calendar year, the Workgroup will document the status of all objectives in the work plan for the year and create a detailed work plan for the upcoming year. Both documents will be submitted to the Executive Leadership Committee for approval.

8 TECHNICAL ADVISORY COMMITTEE (TAC)

- 8.1 Role and responsibilities
- 8.1.1 Reviews strategies, deliverables of workgroups for redundancies.
- 8.1.2 Provides oversight and direction to the Workgroups.
- 8.1.3 Acts as the technical liaison for the ELC and the Workgroups.
- 8.1.4 Assigns, prioritizes, and oversees Workgroup activities.
- 8.1.5 Holds scheduled teleconferences to discuss status and progress of required Workgroup deliverables.
- 8.1.6 Resolves issues that cannot be resolved within the Workgroups.
- 8.1.7 Ensures assigned ELC action items are completed.
- 8.1.8 Delivers TAC and Workgroup progress reports to the ELC as requested.

- 8.1.9 Reports and informs ELC of new issues, which cannot be resolved by the TAC, as they arise.
 - 8.1.10 Recruits industry subject matter experts for workgroups.
 - 8.1.11 Assigns and oversees Workgroups to develop work plans and the execution of their plans.
 - 8.1.12 Represents and reflects the view of the industry not a company- or segment-specific view.
 - 8.1.13 Work products / guideline are reviewed for accuracy, completeness, alignment sent to ELC with approval recommendation.
- 8.2 TAC composition / membership
- 8.2.1 The TAC will consist of approximately ten (6-10) individuals representing the Workgroup co-chairs or senior advisors of the workgroups.
 - 8.2.2 The facilitator for the TAC will be a GS1 US staff representative.
- 8.3 TAC team meeting frequency and agenda
- 8.3.1 TAC meetings will be quarterly.
 - 8.3.2 Ad hoc meetings will be convened as situations warrant.
 - 8.3.3 Standing agenda items for the quarterly meetings will be:
 - 8.3.3.1 Report from each of the workgroups against the yearly plan with deliverables, and assistance needed.
 - 8.3.3.2 Report of work planned for the next quarter and any assistance needed.
 - 8.3.3.3 Other topics as the needs occur.

9 ROLE OF GS1 US

- 9.1 Support GS1 Healthcare US objectives.
- 9.2 Facilitate and support the Executive Leadership Committee, TAC and the Workgroups.
- 8.3 Provide GS1 Healthcare US with current and relevant information about the work areas and outputs.
- 9.4 Provide relevant communication to GS1 Healthcare US.
- 9.5 Ensure GS1 Healthcare US has sufficient support from GS1 US.
- 9.6 Drive alignment of GS1 Healthcare US goals and objectives with those of GS1 Healthcare.
- 9.7 Ensure all of GS1 US is familiar with the work of GS1 Healthcare US.
- 9.8 Ensure that all work is aligned with other initiatives within GS1 US.
- 9.9 Ensure the Workgroups uphold the GS1 US antitrust and code of conduct standards.

- 9.10 Ensure that 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.

10 MEETINGS

10.1 Frequency

- 10.1.1 There will be at least one 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.
- 10.1.2 The majority of the work of the Executive Leadership Committee and Workgroups and TAC will be accomplished via teleconferences.
- 10.1.3 Teleconferences will be convened as required by the Executive Leadership Committee TAC and Workgroups.

10.2 Antitrust and Code of Conduct

- 10.2.1 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.

10.3 Minutes

- 10.3.1 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 normally five business days after the meeting.

11 DOCUMENT DEVELOPMENT PROCESS

- 11.1 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.

12 COMMUNICATIONS

12.1 Representing GS1 Healthcare US

- 12.1.2 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.
- 12.1.3 For presentations to third parties, a standard GS1 Healthcare US PowerPoint template will be developed and used. The presentation shall be converted to a PDF document for distribution and/or download.

12.2 Website and Community Room

- 12.2.1 The GS1 Healthcare US website and community room will be maintained by GS1 US.
- 12.2.2 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.

13 FINANCIALS

13.1 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.

13.2 Annual Fee schedule

COMPANY REVENUE:	ANNUAL FEE:
≥ \$500 MM	\$10000
≥ \$100 MM & < \$500 MM	\$5000
< \$100 MM	\$2000
HOSPITALS/PROVIDERS	\$500

13.2.1 Manufacturers and distributors must have a GS1 Company Prefix and be a member of GS1 US Partner Connections. Hospitals/healthcare providers and GPOs must have a subscription to the GS1 US GLN Registry.

13.3 Industry associations, government regulatory agencies/authorities, and educational institutions are exempt from membership fees.

13.4 Conference fees will be charged to cover cost.

13.5 Payment of GS1 Healthcare US membership fees does not change existing GS1 US fees, such as Partner Connections, GLN Registry™ and 1WorldSync.

14 REVISION RECORD

RELEASE	APPROVAL DATE	CHANGE
1.0	May 22, 2008	First version issued
1.1	December 10, 2010	Section 6.1: Added two Solution Provider, non-voting positions to the GS1 Healthcare US Executive Leadership Committee.
1.1	December 10, 2010	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 6.1.1.2, 6.1.1.5, 6.1.2 6.2, 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 Executive Leadership Committee organization.



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IAPMO

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