

## 1. Vision

The vision of GS1 Healthcare is 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.

## 2. Mission

GS1 Healthcare is a voluntary, global Healthcare user group, which brings together all related Healthcare stakeholders. Its mission 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.

## 3. Accountability

GS1 Healthcare reports to the GS1 Management Board.

## 4. Membership

There are two classes of membership:

- Voting: Voting members are normally required to pay membership dues.
- Non-voting: Non-voting members are not required to pay any membership dues.

### 4.1 Voting Membership Criteria

GS1 Healthcare Voting Members must be a member company of a GS1 member organisation. Members can be manufacturers, wholesalers/distributors, GPO's, hospitals, pharmacies, logistics, and technology or solution providers. More than one individual can represent voting member companies (as defined in Section 4.1 paragraph 1); however, each member company has only one (1) vote, even if they have multiple divisions.

Voting members of GS1 Healthcare contribute to GS1 Healthcare activities and basic operational costs with an annual fee to GS1 Healthcare. Members are only eligible to vote once they have paid their annual membership dues. For renewals, fees are due on the 31<sup>st</sup> of March.

Voting members have voting rights in the development of global standards and password-protected access to all documents and the Public Policy database. They can be candidates for the Leadership Team and the chair positions.

## 4.2 Limits of Authority

Decision-making is achieved through consensus, which is defined as approval without sustained opposition – a quorum of 50% is necessary.

Plenary decisions of GS1 Healthcare: Plenary decisions of GS1 Healthcare require the approval of 66% of the members that are entitled to vote - a quorum of 50% is necessary. In addition a simple majority of each (a) manufacturers and of (b) wholesalers/distributors, GPO's, hospitals, pharmacies and logistics providers c) technology and solution providers, must be reached in order for a decision to be taken. Voting will normally be done by e-ballot and the vote must be given within 10 working days.

GS1 Healthcare work team decisions: Decisions of GS1 Healthcare work teams (e.g. Public Policy, Healthcare Provider Advisory Council) require the approval of 66% of the members of that work team that are entitled to vote - a quorum of 50% is necessary. Voting will normally be done by e-ballot and the votes must be given within 10 working days.

Leadership Team decisions of GS1 Healthcare - In the case of sustained opposition, the reasons shall be documented and the Leadership Team can make a decision with a 66% majority with all members of the Leadership Team being required to register their vote. The voting will take place via e-ballot. The votes must be given within 10 working days – otherwise abstention is assumed. Votes which are No shall include an explanation of the rationale behind the vote. Any deviation from the defined voting criteria must be documented and approved by the Leadership Team.

GSMP decisions and process – The processes and decision making rules for GSMP are contained in the GSMP Users Manual (see section: Sector Specific Processes). Since 19 April 2010, any company wishing to participate in new GSMP Groups must sign the GS1 IP Policy and Opt-In Agreement <http://www.gs1.org/gsmg/gsmg/ip>. All proceedings will be minuted and recorded for future reference.

GS1 Global Office supports and manages the decision process but has no voting privileges.

## 4.3 Non-voting Membership Criteria

Organisations with a keen interest in standards development and patient safety may support GS1 Healthcare by participating in the Work Teams. Non-voting members are eligible to become members of GS1 Healthcare Work Teams, attend GS1 Healthcare events, and will have access to standards development Work Team documentation, but will not have voting privileges.

Non-voting membership is limited to trade associations, regulatory bodies, educational institutes and other standards bodies. All other organisations and firms are eligible for voting membership.

## 5. Fees

GS1 is a not for profit global standards organisation. GS1 Healthcare is a GS1 facilitated global Healthcare user group. GS1 Healthcare activities are funded from the fees of voting members of GS1 Healthcare. Fees are collected from voting members on a cost recovery basis. The funds collected are to cover the cost of the meetings and activities of GS1 Healthcare. Activities are determined by the Leadership Team and are adjusted based on forecasted funding levels.

Membership fees are due on the 31<sup>st</sup> of March each year. Members in default of payment after the first quarter of the year will not be allowed to participate as voting members after the first quarter of the calendar year.

Conference fees will be different for voting GS1 Healthcare members and non-voting GS1 Healthcare members and be determined according to the local culture.

A financial review with the GS1 Healthcare Leadership Team shall be conducted three times annually.

## 6. Organisational Leadership

### 6.1 Leadership Team

To be elected to the Leadership Team or maintain representation on the Leadership Team, representatives must be GS1 Healthcare Voting Members in good standing.

The Leadership Team shall optimally comprise of a range of ten (10) voting to twenty (20) voting members from the user community. Voting membership should be balanced across regions, the Healthcare supply chain, and industry. Qualifications to serve as a Leadership Team member include subject matter expertise in the GS1 System and associated technologies.

GS1 Member Organisation representatives (maximum 6) may also serve as additional -voting Leadership Team members. The representatives represent all geographic regions and are nominated by the CEO of their organisation either via the GS1 Advisory Council or directly to the GS1 CEO. They must be able to represent their colleagues/region in discussions and decisions. The GS1 Advisory Council decides on the representation from the MO's if there are more nominations than places. If the replacement of an representative is necessary this will be communicated also by the MO CEO to the GS1 CEO and the AC.

Leadership Team members will also be engaged in GS1 Healthcare Work Teams and will take responsibility for leading one Work Team during their term or serve at least as a liaison to one.

As regular participation is key to the effectiveness of the Leadership Team, if a Leadership Team member is absent for more than 6 successive Leadership Team calls and/or meetings and does not attend two of the global conferences/video conference in

in a row, the Leadership Team has the authority (but not obligation) to remove the member from the Leadership Team.

## *Roles and Responsibilities*

The Leadership Team shall

- Elect Tri-Chairs through nomination and consensus.
- Develop and maintain the overall GS1 Healthcare strategy and timeline for successful development and implementation of global standards
- Review and approve: finances (three times per year), conference/meeting planning, public relations, membership and policy
- Work with the Public Policy Work Team to develop the strategy to carry the GS1 standards message to the government bodies regulating the Healthcare industry
- Ensure geographic and supply chain stakeholder balance at the Leadership Team level
- Represent GS1 Healthcare membership to external groups and organisations with interests in standards and patient safety - GS1 representatives shall be engaged.
- Create Work Teams to respond to, or drive, specific initiatives
- Develop a process to ensure that Work Teams are adequately resourced and geographic and supply chain stakeholder balance is obtained
- Appoint Work Team leaders, review progress of the Work Teams on a regular basis and ensure that there is alignment between the Work Teams.
- Ensure participation and represent GS1 Healthcare in the Global Standard Management Process (GSMP) and the GS1 governance groups.
- Approve Healthcare Work Requests (WR's) to progress work into GSMP
- Ensure that all plenary decisions taken are in alignment with the mission and vision. The Leadership Team has veto power over any decision
- Ensure regularly communication to the global GS1 Healthcare membership community to update and engage them through various mechanisms to increase awareness of ongoing global activities and to solicit participation in the discussions, workgroups and all other global GS1 Healthcare activities.
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- Provide leadership in resolving conflict

Leadership Team members must be able to represent their organisations and segment of the supply chain in key-decisions.

The Leadership Team shall hold regular scheduled teleconferences to monitor progress, discuss issues and meet in person in conjunction with GS1 Healthcare Conferences. Additionally at minimum one video-conference will be scheduled per year. Further face-to-face meetings can be organised if necessary.

### *Leadership Team Selection Process*

A candidate to the Leadership Team must be engaged in GS1 Standards development efforts and should be able to promote the implementation of the developed global standards and best practices in their organisations and should therefore be able to provide linkage between their organisation and GS1 Healthcare. An election committee, consisting of GS1 Healthcare Tri-Chairs and the GS1 Global Office, shall present suitable candidates to the membership for selection. Membership confirmation is obtained by e-ballot of the membership when there are more candidates than positions. Requests for LT membership or replacement of LT members through colleagues during the term of office are decided through eBallot of the LT or like in US version: In the event that a Leadership Team member leaves the Healthcare Community, the position held by that member will immediately be open for re-election. In the event that a Leadership Team member changes their healthcare category during a serving term, the Leadership Team will decide whether or not the member should serve to the end of the subject year

GS1 Member Organisations are nominated by their regions/organisation.

### *Term Limits*

Leadership Team members serve a one-year term which is renewable.

## 6.2 Tri-Chairs

The Leadership Team shall elect Tri-Chairs through nomination and consensus. The Tri-Chairs should provide adequate representation from all Healthcare sectors and an attempt should be made to keep a geographical balance.

### *Roles and Responsibilities*

Tri-Chairs shall:

- Convene and preside at GS1 Healthcare conferences and meetings

- Approve Leadership Team Meeting agendas proposed by the GS1 Director Healthcare.
- Facilitate the consensus process
- Disseminate and monitor communications with membership
- Report to the GS1 Management Board

### *Term Limits*

Tri-Chairs serve a term of 2 years with the possibility to be re-elected for another two years. Tri-Chair terms are staggered to ensure continuity. GS1 staff cannot serve as Tri-chairs.

### 6.3 Work Teams

GS1 Healthcare develops global standards following the GSMP process. These Work Teams focus on specific business issues and follow the GSMP rules as outlined in the GSMP manual. The working language is English.

All development Work Requests (WRs) for Healthcare are reviewed by the Leadership Team and development WR's which apply only to Healthcare are progressed in GSMP after approval through the Leadership Team.

### 6.4 Work Team Leaders

Work Teams are ideally Co-Chaired and the chair(s) should be confirmed by the LT.

### *Roles and Responsibilities*

- Ensures the progress of the team according to the scope and deliverables
- Ensures adequate and representative participation during discussions
- Provides administration for all team activities, and will be supported in that task by staff from GS1
- Reports on the progress of their Work Teams to the Leadership Team on a regular basis

### *Term Limits*

Work Team Leaders maintain their position for the duration of the Work Team's existence.

### 6.5 Director Healthcare

## *Roles and Responsibilities*

- Facilitates GS1 Healthcare decisions
- Executes the Leadership Team's strategy
- Coordinates Marketing & PR Responsibilities for Healthcare with GS1 staff
- Provides general communication
- Reports to the GS1 Global Office (GO) Management
- Ensures that the GS1 Healthcare Leadership Team has sufficient support from GS1 staff and provides the Leadership Team with an overview of resources available for projects.
- Drives GS1 alignment with GS1 Healthcare goals and objectives
- Is accountable to the President GS1 Industry Engagement and the Leadership Team
- Coordinates relations with other organisations/associations

## *Term Limits*

Director Healthcare maintains the position as long as he/she remains in his/her post.

## **7. Conferences and conference procedures**

There will be two global conferences per year. The GS1 Healthcare Leadership Team decides the dates and venues. The conferences should take place in different geographical locations. The agenda of the conferences are drafted by the marketing manager in alignment with the Director Healthcare and approved by the Leadership Team.

### 7.1 Conference fees

There are fees applicable for conferences; GS1 Healthcare voting members and associations pay a reduced fee.

The following participants shall attend conferences free of charge: speakers, hospital staff and regulatory bodies,

GS1 Global Office and the Tri-Chairs decide if GS1 Healthcare will reimburse the travel costs for a speaker – there will be no remuneration for speakers.

## 7.2 Anti-Trust Statement

The GS1 Anti-Trust Statement must be brought to the attention of all participants at the beginning of each conference/meeting and teleconference.

## 7.3 Code of Conduct

GS1 Healthcare members will adhere to the Code of Conduct (Appendix 2).

## **8. Communication**

### 8.1 Document Development Process

#### *Specific Responses regarding public policy*

The Public Policy Work Team shall be ultimately responsible for drafting and approval of specific responses with subject matter support from the GS1 Global Office. The Leadership Team then reviews the proposed response and informs the full membership. Substantive and editorial changes are suggested and approved by consensus (as defined in Section 4.2 Limits of Authority). Review can be via a physical meeting, e-mail, teleconference or Webex™, led by the Work Team “Public Policy”. GS1 Healthcare will submit the response to the regulatory authorities either via the local GS1 Member Organisation or through the President of GS1 or the Director of GS1 Healthcare.

#### *Position Papers & Position Statements*

Any member of GS1 Healthcare or a GS1 Member Organisation can draft a GS1 Global Healthcare position paper or position statement. Once drafted, the document shall be submitted for approval to the GS1 Healthcare Leadership Team for adoption. Substantive and editorial changes are suggested and approved by consensus (as defined in Section 4.2 Limits of Authority). Review and adoption can be via a physical meeting, e-mail, teleconference or Webex. If time permits, the document will also be sent to the full membership for information and feedback within defined time limits. Once the Leadership Team and originator reach agreement the position paper or position statement can be posted on and distributed via the GS1 Healthcare website.

#### *Press Releases*

A press release is a succinct and timely announcement. Agreements among Healthcare stakeholders, regulatory bodies and key customers, and organisations adoption of GS1 Standards, or a change in GS1 Healthcare Leadership are possible press release topics. Topics must be presented to the GS1 Healthcare Leadership Team before forwarding to GS1 GO Marketing to draft and publish.

## 8.2 Communication process

Communication with associations and regulatory bodies, on global issues, is done through the Director of Healthcare in conjunction with the Tri-Chairs and members of the Leadership Team from the geographic region impacted. The communications will be according to the mission and strategic plan of GS1 Healthcare. When the association and/or regulatory topic is for a specific geographic area the MO and MO's involved with this geographic area will take the lead in communications in collaboration with the Director of Healthcare and consistent with the GS1 Healthcare global mission and strategic plan.

GS1 Healthcare provides the neutral platform with its members in discussions between Healthcare stakeholders and regulatory bodies.

Communication, with regard to GS1 Healthcare global marketing activities, shall be reviewed by the Leadership Team and in alignment with the GS1 branding guidelines. GS1 GO shall maintain the GS1 Healthcare website ([www.gs1.org/healthcare](http://www.gs1.org/healthcare)), brochures, newsletters, etc.

## Annex:

### How to Use This Document – Document Conventions

**MUST:** This word, or the terms "REQUIRED" or "SHALL", means that the definition is an absolute requirement.

**MUST NOT:** This phrase, or the phrase "SHALL NOT", means that the definition is an absolute prohibition.

**SHOULD:** This word, or the adjective "RECOMMENDED", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT:** This phrase, or the phrase "NOT RECOMMENDED", means that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

**MAY:** This word, or the adjective "OPTIONAL", means that an item is truly optional.

## Appendix 1. Code of Conduct

### Principles

One of GS1 Healthcare's greatest and proudest strengths is the rich diversity of people and businesses that work with the organisation and attend meetings. We recognise that, not everyone is used to working in such a diverse group, and therefore draw your attention to basic principles and standards of behavior that apply at all meetings.

Comments on the following subjects may cause offense and are not acceptable, however intended:

- Race, national identity, national language or nation of origin. All races and nations are equal at GS1 Healthcare;
- Age, gender, sex, or sexuality. Men and women of all ages and backgrounds are treated as equals;
- Disparaging remarks about companies, types of companies or industries. We welcome all types and sizes of enterprise from all industries.

GS1 Healthcare is a place where buyers and sellers meet, however:

- Presentations and remarks may not promote or attempt to sell a particular company, proprietary product or product type, implicitly or explicitly;
- These are strict networking opportunities and should not be used to conduct company business or sales opportunities. Therefore, please arrange a private follow-up visit outside of times organised for breaks and social gatherings if you choose to engage in company business matters.
- GS1 Healthcare depends on a constructive spirit of innovation. You are welcome to be as positive or sceptical as you like about prospects, but you should respect the views and credibility of others, especially those with credentials and training in their field. Do not denigrate individuals or their ideas just because you disagree with them about whether or not something is possible.

## Revision record

Version	Date	Changes	Responsible
1.0	18.09.2006	Final version for LT Meeting in Paris	Ulrike Kreysa
1.1	26.09.2006	Feedback from LT discussion in Paris incorporated	Ulrike Kreysa
1.2	08.10.2006	Final document for LT vote with changes after comments from Mark, Peter and Jim	Ulrike Kreysa
1.3	11.10.2006	Inserted background about status of non-for-profit for GS1 and fees are used to cover GS1 Healthcare activities according to work plan. Voted on and approved by GS1 Healthcare Leadership Team	Ulrike Kreysa
1.4	27.02.2007	Changed title and HUG references to GS1 Healthcare; all other changes in red.	George Simeon
1.4.1,2	25.06.2007	Reviewed full Charter	HUG-HLS Charter Work-Team
1.4.3	09.07.2007	Final Working Draft for review by HUG & HLS LT.	HUG-HLS Charter Work-Team
1.4.4	10.07.2007	Draft Reviewed by HUG & HLS LT. Work-team to address industry representation and balance issues. Code of Conduct to be inserted in section 6	HUG-HLS LT
1.4.5	01.08.2007	Final Draft document: Changed section 5.1; Added section 6.5; Appendix 1; Appendix 2.	HUG-HLS LT
1.4.6	15.11.2007	Final Draft document including feedback from HUG-HLS LT meeting of 28 October 2007	HUG-HLS LT
1.4.7	19.12.2007	Final Draft document including feedback from HUG-HLS LT conference call of 17 December 2007	HUG-HLS LT
1.4.8	07.01.2008	Final draft document including decision from LT to allow associations to participate to conferences at the conference fee for voting members	HUG-HLS LT
1.4.9	05.11.2008	Changes as discussed and agreed in LT meeting in Tokyo	Ulrike Kreysa
1.5	08.06.2009	Governance Charter 2009 Review and Revisions	George Simeon
1.5.1	15.06.2009	Review and Edits at LT meeting in Washington	Ulrike Kreysa / George Simeon
1.6	27.01.2010	Changes related to Tri-Chairs, solution provider participation and editorial corrections	Ulrike Kreysa/Jan Denecker/Jim Willmott
1.7	06.06.2010	Changes related to conferences and voting for GS1 MO's	Ulrike Kreysa
1.8	January 2011	Changes related to eBallots and other changes following discussion in Singapore	Ulrike Kreysa