

Global Harmonization Task Force Steering Committee Reference Guidance -- GHTF Training

1.0 Background and history: During the third meeting of the GHTF Steering Committee (London, October 2001), members discussed policy considerations related to GHTF training, the handling of any formal requests for training, and a proposal to establish a "GHTF Training Institute". The Committee agreed that a working group should prepare for further consideration a framework document addressing the future conduct of GHTF training. That proposed document was accepted in substance at the fourth meeting of the Steering Committee (Singapore, May 2002).

2.0 Objectives: As part of its Strategic Direction, GHTF has adopted as a goal:

GHTF members will support and advocate the adoption of the global regulatory model in their own systems and those of other countries/regions

3.0 Definitions: GHTF-related training may take two forms:

3.1 GHTF training: Training, offered under the auspices and with the authority of GHTF, which is directly related to GHTF core activities. Training activities commit GHTF and participants and are part of the GHTF work programme. As such, they are approved by the Steering Committee.

3.2 Training on GHTF: Training that provides general information about, and raises general audience awareness of, GHTF recommendations and activities, but which is not offered under the auspices and under the authority of GHTF. These activities will normally be part of national programmes, commercial events, or industrial co-operation; they do not commit GHTF and are not subject to approval by the GHTF Steering Committee.

GHTF-related training is in addition to other mechanisms for the dissemination of GHTF work products, e.g., the GHTF website.

Events in which training on GHTF is provided will probably be held more frequently than GHTF training.

4.0 GHTF training:

4.1 Examples:

- 4.1.1** Preparation for participation in a GHTF system or project, e.g., the exchange of vigilance information
- 4.1.2** Training requested by affiliated regional parties, e.g., Asia Harmonization Working Party
- 4.1.3** Training requested by cooperating entities, e.g., World Health Organization
- 4.1.4** Specific training event associated with a GHTF conference

4.2 Guidance:

- 4.2.1** The scope and content of such an event shall be predominantly, but not limited to, GHTF recommendations, including how members use GHTF documents
- 4.2.2** The training session event, agenda, and speakers must be endorsed by the GHTF Steering Committee
 - 4.2.2.1** Endorsement does not imply that GHTF will necessarily provide funding for the event. Such events will be funded by the sponsor and/or through existing GHTF cooperative funding mechanisms.
- 4.2.3** Publicity and press releases must be reviewed and approved by the GHTF Chair or his/her delegate
- 4.2.4** The event shall be publicised on the GHTF website
- 4.2.5** Speakers shall use the standard GHTF slide template
- 4.2.6** Training events shall be reported on during GHTF Steering Committee meetings and GHTF conferences.

5.0 Training on GHTF:

5.1 Examples:

- 5.1.1** Presentations on national regulatory systems which include the effects of GHTF on national systems;
- 5.1.2** Training sessions as part of co-operation programmes between GHTF regulatory members and third countries or other regions, e.g. on national regulation, international regulatory convergence, trade facilitation.
- 5.1.3** Events organised by industry representatives of GHTF member countries
- 5.1.4** Commercially organized events on medical device regulation
- 5.1.5** Training events organized by countries not participating in GHTF

5.2 Guidance:

- 5.2.1** GHTF members are encouraged to participate in such events.
- 5.2.2** In addition to speaking about their “home” regulatory systems and how or why they differ from GHTF recommendations, speakers may speak about GHTF and its activities and effects on national systems.

6.0 General guidance:

To the extent that guidance can be given by GHTF on training events in which GHTF activities are being presented, GHTF members are encouraged to observe the following guidelines:

- 6.1** Where appropriate, the speaker should specify the position he/she is speaking from (i.e., member of GHTF Study Group, GHTF Steering Committee, industry, regulator, interested party, Founder Member/Task Force member).
- 6.2** Emphasis should be given to GHTF documents that have reached “final” stage (as the others are still subject to change), but it is recognised that speakers may also discuss “work in progress”.
- 6.3** Citations to GHTF documents should clearly specify the document status (i.e., working draft, proposed, final).
- 6.4** It is appropriate to outline the Study Group work programmes so that the audience can see the general context and direction of GHTF work.

- 6.5** The speaker should make a clear distinction between positions as expressed in GHTF documents and the personal/national/interest views of the speaker, in particular where the speaker is involved in GHTF activities
- 6.6** Copies of presentations may be posted on the GHTF website.

7.0 Website:

- 7.1** GHTF should establish an information page on the GHTF website which lists GHTF training events and their agendas. The site may also include reference to training events on GHTF, where the GHTF secretariat has been informed of such events. The site may also include copies of presentations given.