

NOTE: The following relates to a “Guiding Principles” Summary for the Global Harmonization Task Force. An Annex (to be developed) will expand on the procedural aspects in support of this “Guiding Principles” Summary, taking into account identified aspects in the draft operating Principles and Procedures document.

I. INTRODUCTION

During the first seven years of the GHTF, a strong partnership has been built between the founding members represented by regulators and industry, identified as three regions (a) EEC + EFTA, (b) USA + Canada, (c) Japan + Australia.

Since its inception the GHTF has adopted an 'informal approach'. Although the members want to continue to adhere to this principle, it was agreed that some form of guidance should be provided in order to proceed in an orderly manner.

This document summarises the main principles of operation and more detailed guidance is can be provided in anthe annexed procedures document.

II. GOALS, OBJECTIVES AND GOVERNING PRINCIPLES

II.1 GOALS

- The primary goal of the GLOBAL HARMONIZATION TASK FORCE (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices aiming to ensure a high level of health protection, facilitating trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be the most suitable, sharing experience on regulatory systems. Technical aspects should be emphasized instead of setting regulatory requirements

II.2 OBJECTIVES

- i) To facilitate market access for medical devices and eliminate multiple controls that are not justified to assure medical device safety and effectiveness
- ii) To create a flexible regulatory environment for the introduction of beneficial new technology
- iii) To share experiences with and encourage participation in discussion from other countries both inside and outside the founding membership
- iv) To encourage participation in discussion from countries both inside and outside the founding membership.
- v) To streamline exchange of information – to assist in the protection of public health.

II.3 GOVERNING PRINCIPLES

- i) Maintain an informal approach
- ii) Decision by consensus
- iii) GHTF has no legal status and therefore the output is not mandatory
- iv) Equal Partnership between Regulatory Authorities and Industry throughout all GHTF activities
- v) The three founding regions (a) European Union/EFTA, (b) USA/Canada, (c) Japan/Australasia are the CORE Group and responsible for management of the Task Force
- vi) Output of GHTF to be widely disseminated
- vii) The perspective is 'Global'
- viii) Transparency of process

- ix) English is the operating language

III. MEMBERSHIP

III.1 CORE GROUP

The three founding member regions (a) European Union/EFTA, (b) USA./Canada, (c) Japan/Australasia.
Other countries may be invited by one of the founding member regions to participate within that region.
Study Group chairs to participate in the core group as invited.

III.2 Other members

- i) Any individual country may apply for membership
- ii) Countries may combine their participation into groups (e.g. an Asian Grouping or the Mercosur Group)
- iii) Countries may decide to link to GHTF via one of the founding members, if invited by that region.

III.3 Observers

ISO and WHO are currently observers. Other relevant organisations may be invited as observers at GHTF meetings.

IV. ACTIVITIES AND OPERATIONAL PROCEDURES

IV.1 REPRESENTATION AT GHTF PLENARY MEETINGS

- i) The Chair and Vice Chair of the GHTF as appointed (see below).
- ii) CORE Group represented by :
 - up to 4 representatives of Regulatory Authorities from each of the three founding members regions.
 - up to 4 Industry representatives from each region
 - each region to decide on the process of selecting Regulatory and Industry Representatives
- iii) Other members represented by :
 - for individual country members two representatives total from the regulatory authorities and industry
 - for other regional groups the number of representatives from regulatory authorities and/or industry will be balanced with other, similar groups.
- iv) Study group Chairs
- v) observers

V. GHTF CORE GROUP

Management Responsibilities of the core group.

- i. establish work objectives and priorities for the GHTF
- ii. ensure achievement of goals and objectives
- iii. appoint/disband GHTF Study Groups and establish Terms of reference
- iv. appoint GHTF Study Group Chairmen
- v. establish Terms of Reference of GHTF Study Groups
- vi. approve/propose new work items or revisions to GHTF Study Group work programme
- vii. delete existing working items/obsolete documents, where appropriate
- viii. approve GHTF Study Group documents
- ix. assign/review status of GHTF Study Group documents from time to time

VI. PROCEDURE AT GHTF PLENARY MEETINGS

Meetings to be held every 12 to 18 months to: a) to discuss matters relating to functions in V.i) above and b) to make decisions as requested

- a) receive Reports from the Chair
- b) receive Study Group progress reports
- c) receive reports from members
- d) discuss matters raised by founding members
- e) receive report and discuss matters raised by other members

VII. REGIONAL/INDIVIDUAL MEMBER PROCEDURES

Each region organises itself in relation to GHTF plenary and Study Group matters

All members have access to work emanating from the Global Harmonization Task Force Study Groups

VIII. GHTF CHAIR AND VICE CHAIR

- i) Designation
 - rotation between the 3 founding member regions
 - nominations for these positions to be the responsibility of the regulatory representatives of the region concerned.
 - Co-chair may be held by industry representative of the region concerned
 - period of office not to exceed 3 years
- ii) Function
 - Convene and chair GHTF meetings
 - Provide, establish secretarial service function
 - Supervise management functions for GHTF

IX

Delete, tasks should be assigned to the core group

X GHTF STUDY GROUPS

i) GHTF Study Groups

- established by the GHTF to carry out work and prepare documents on assigned subjects using the agreed Terms of Reference as indicated in the attached procedures guidance document
- Will meet as required
- membership to include broad representation from Regulators and Industry with appropriate knowledge, others by invitation only.

ii) GHTF Study Group Chairs

- Study Group Chairs are appointed by the Core Group GHTF, representatives from regulators or industry may hold this position
- Study Group Chairs shall be responsible for organising meetings, discussing assigned tasks and developing documents as required
- circulate drafts and agendas and produce reports as indicated in the procedures guidance document
- Study Groups will circulate documents for comment as indicated in the Document Process Description procedure
- Open and non-attributable discussions will be encouraged during GHTF Study Group meetings. Minutes or as a minimum, an agreed action list will be made available via for the Chair in a timely fashion. Members and observers will be discouraged from publicising personal notes
- The Study Group Chair will be responsible for controlling the management of participation at Study Group meetings within rules agreed by the core group.

XI. DOCUMENTATION CLEARANCE PROCESS

XI.1 BASIC PRINCIPLES

- i) GHTF documents should only be developed on a) fundamental aspects of medical devices regulation and b) where there is a demonstrable need for guidance.
- ii) Comments on emerging regulations, or regulations being amended, are intended as recommendations to encourage for alignment of regulatory requirements.
- iii) GHTF documents endorsed by the GHTF are available for consideration in relation to future development of regulatory schemes.
- iv) Work items should not overlap with standardisation activities.
- v) GHTF endorsed documents will be made freely available for consideration.
- vi) GHTF documents do not have an official status but are intended to offer sound advice based on experience.
- vii) A proposed Work Item shall be accompanied by a comprehensive justification
- viii) GHTF documents should not restrict the flexibility inherent in the regulations.

XII DOCUMENT PROCESS DESCRIPTION

Stage 1 - New work items shall be approved by the Core Group/GHTF and assigned to a Study Group who will establish work priorities.

Stage 2 - Study Group develops a Working Draft based on input from all interested parties.

Stage 3 - After reaching internal consensus, Study Group Chair circulates Working Draft to other Study Groups and outside parties for timely review and comment.

Stage 4 - Following incorporation of all appropriate comments, the Study Group Chair presents the Working Draft via the GHTF chair to the Core Group via the GHTF chair, which approves/ disapproves its status as a Proposed Document.

Stage 5 - Once Working Draft is advanced to Proposed Document stage, GHTF Chair posts the document on the GHTF website and by any other means for regional/national/public review (for 3 months unless extended/reduced by the GHTF); Study Group collates comments and makes changes, as appropriate.

Stage 6 - Study Group Chair sends Final Document to the Chair of the GHTF with a request for endorsement and approval.

Stage 7 - GHTF Chair endorses/rejects document based on the consensus obtained at the Core Group.

Stage 8 - GHTF Chair publishes GHTF document as Final Document and puts it on GHTF Internet Web site for information to whoever is concerned.

Notes:

- 1) At any stage, the GHTF may decide to interrupt the process for any work in progress and ask the Study Group to terminate the work item and/or document. Similarly, the Study Group may seek approval to discontinue any work item on its programme.
- 2) At all stages of the procedure to develop a document there should be consultation on a broad basis with all interested parties.
- 3) All document development should be a transparent process.