FINAL DOCUMENT

Global Harmonization Task Force

Title: GHTF Operating Procedures

Authoring Group: GHTF Steering Committee

Endorsed by: The Global Harmonization Task Force

Date: 4 November 2010

Dr Larry Kelly, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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Preface

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from the European Union (EU) and EFTA (European Free Trade Association), the United States of America (USA), Canada, Japan and Australia.

The original version of this document was endorsed by GHTF in September 2000 and it was foreseen at that time that the text would undergo periodic revisions. A review of this document was undertaken in 2005. A further revision occurred in 2009 to address document translations and to incorporate process improvement changes adopted by the Steering Committee at its 16th meeting. A further review was undertaken in 2010. This text is the result of those reviews.

1.0 Introduction

This document is intended to describe the basic procedures that the Global Harmonization Task Force (GHTF) follows in developing GHTF documents.

The Operating Procedures outlined in this document, in conjunction with the "GHTF Roles and Responsibilities" and "GHTF Guiding Principles" and the "GHTF Strategic Directions", are designed to be flexible so that should the need arise, the GHTF can respond to challenges with respect to its objectives in a timely manner.

2.0 Language

The GHTF working language, written and spoken, is English. Translation of GHTF work products into other languages is the responsibility of each individual member wishing to do so. Translations of GHTF work products are not reviewed for accuracy by GHTF. (See also Section 8 below)

3.0 GHTF Document Management

The procedures set forth in this section apply to all guidance documents which are intended to be published on the website as Final Documents.

Annex A provides a schematic overview of these procedures. Annex B provides an overview of the different types of GHTF documents.

To enhance transparency a procedural sheet following the format included in Annex C and a Document Transmittal Record (Annex F) will be drawn up and kept with each GHTF document.

3.1 General Principles

Any new work item for either a Study Group or an Ad Hoc Working Group must have a clearly articulated scope and a timeline for key milestones and delivery.

Study Groups and Ad Hoc Working Groups should liaise by e-mail or teleconference as often as required to meet the agreed timelines. It is the responsibility of each Chair to ensure that work is allocated equitably among group members.

Study Group and Ad Hoc Working Group Chairs must provide a brief written report to each Steering Committee meeting held face-to-face, on progress against milestones and participation by members.

Where a Study Group or Ad Hoc Working Group is unable to meet the milestones and final delivery timeline, the Steering Committee may consider alternatives to completing the work.

3.2 Stage 1 – Assignment of New Work

The GHTF Steering Committee will consider at each face-to-face meeting the need for new work to be undertaken. The GHTF Steering Committee may assign a new work item to an existing Study Group, or establish a Study Group or an Ad Hoc Working Group to undertake the new work item. The GHTF Steering Committee may also direct a Study Group or an Ad Hoc Working Group to undertake the analysis of a new issue. In each of these cases, the GHTF Steering Committee will be responsible for proposing the rationale for the work assignment.

New Work Item referrals should be drawn up following the format attached in Annex D. The GHTF Steering Committee should, in particular, consider the following issues:

- scope, purpose and rationale including an outline of issues to be addressed and opportunities for regulatory convergence,
- relation to the goals set out in the GHTF strategic direction,
- proposed sources of necessary expertise,
- relevant existing documents at GHTF and national level.

The GHTF Steering Committee may allocate priorities to Study Group and Ad Hoc Working Group work items.

It is expected that the assigned new work will be completed by the Study Group or Ad Hoc Working Group within 18 months of referral.

3.3 Stage 2 – Document Development

The Study Group or Ad Hoc Working Group will undertake the development of a Working Draft consistent with the scope, purpose and rationale of the approved new work proposal.

3.4 Stage 3 – Consultation on Working Drafts

Once a Study Group or Ad Hoc Working Group has decided that a Working Draft is suitable for circulation, the Chair should invite members to disseminate the Working Draft to relevant experts amongst their country's regulatory authority and industry association(s) or to external experts.

Working Drafts should, however, not be posted on the GHTF Website and not be publicly available, as they are subject to considerable changes.

Comments should be submitted to the Chair of the Study Group or Ad Hoc Working Group, either directly, or via the country's or industry's representative to the group.

By the time consensus on the revised Working Draft document is reached, the Study Group or Ad Hoc Working Group Chair should have sought the broadest consultation appropriate.

3.5 Stage 4 – Advancement from Working Draft to Proposed Document

Final Working Drafts should be forwarded, in the prescribed GHTF format (see GHTF Style Guide), using the Document Transmittal Record (see Annex F) in electronic format to the GHTF Chair. The GHTF Chair will forward a copy of the document, with the Document Transmittal Record, to the GHTF Steering Committee, which will review the document against the following criteria, before proceeding with the advancement process:

- consistency with the project scope, purpose and rationale as originally approved by the Steering Committee in the New Work Item Proposal, and
- coordination of the project with other Study Group or Ad Hoc Working Group work, where appropriate, and conformity to GHTF procedures with respect to title, numbering and status designation.

The Steering Committee will have eight weeks to review the document.

Decisions regarding Study Group or Ad Hoc Working Group requests for advancement of a document to Proposed Document stage will occur by consensus of the Steering Committee. In the absence of consensus, however, the document in question will be referred back to the Study Group with the reasons for rejection and a specified time period for additional review and direct action[1].

The Steering Committee may also determine that the document should not be advanced further.

The decision of the Steering Committee shall be documented on the Document Transmittal Record, Procedural Sheet (Annex C), and in the record of discussion of the Steering Committee meeting.

3.6 Stage 5 – Consultation of Proposed Documents

All Proposed Documents will be posted on the GHTF website by the Chair through the Secretariat within three weeks of approval as a Proposed Document. Generally, the comment period for Proposed Documents will be six months, starting from the date the document was posted on the GHTF website. This may be modified, however, by individual Study Group or Ad Hoc Working Group Chairs or by the Steering Committee Chair. Study Group or Ad Hoc Working Group Chairs should also indicate an appropriate contact person to whom persons accessing the document via the website can address their comments, using the appropriate format. Documents which remain on the website shall be marked with a disclaimer once the comment period has closed. It shall state that the document is under revision.

It is also recommended that each GHTF Steering Committee member establishes a process for soliciting comments from interested persons and organizations within their area and that Study Group Ad Hoc Working Group members then use this process to solicit comments within their jurisdictions.

All documents should be available in electronic format.

[1] Typically the Steering Committee would provide direction and not redraft the document.

The Study Group or Ad Hoc Working Group will evaluate the comments submitted and issue a revised document expeditiously, generally within six months. The Study Group or Ad Hoc Working Group Chair will inform the Chair and the Steering Committee if more time is needed.

3.7 Stage 6 – Advancement from Proposed Document to Final Document

Once consensus is reached within a Study Group or Ad Hoc Working Group that its work on a document is complete, and that all comments have been appropriately resolved, the Study Group or Ad Hoc Working Group Chair will present the document proposed as final to the GHTF Steering Committee's Secretariat using the Document Transmittal Record (Annex F). The following mechanism will then be used to obtain GHTF endorsement as a Final Document:

The Steering Committee will then have eight weeks to review the document.

Generally, decisions regarding Study Group or Ad Hoc Working Group requests for endorsement of a Final Document will occur by consensus of the Steering Committee; however, in the absence of consensus, the document in question will be referred back to the Study Group or Ad Hoc Working Group with the reasons for rejection and a specified time for additional review, modification and re-submission.

The Steering Committee may also determine that the document should not be advanced further.

The decision of the Steering Committee shall be documented on the Document Transmittal Record, Procedural Sheet (Annex C), and in the record of discussion of the Steering Committee meeting.

Endorsement of the document will be formalized with the signature of the current GHTF Chair on a standardized cover page (see Annex E), authorizing publication as a GHTF document. The signature may be given in electronic format.

Signature by the GHTF Chair signifies acceptance of the Final Document by all members on the Committee and their commitment to promote it within their respective country or international organization of states, and, in the course of time, to seek convergence of regulatory practices.

3.8 Stage 7 – Publication

Once endorsement of a Final Document is obtained, the Chair will make the necessary arrangements to post it in electronic format on the GHTF website.

Posting on the GHTF website will include a contact name and e-mail address generally of the Study Group Chair or Secretariat.

In addition, an electronic notification on the availability of the signed-off document on the GHTF's web site will also be sent by the GHTF Chair to the Steering Committee Members for the purposes of general reference and potential adoption.

4.0 Document Status Designation

Documents will bear appropriate identification codes.

The document identification practices described below are intended to apply to all GHTF outputs created by any person or group involved in GHTF activities.

4.1 Location of Designation Code

All GHTF documents are to have their official designation code noted in the upper right hand corner of the cover sheet.

Each document is designated a document number, which remains the same throughout the development of the document. The Secretariat will distribute the document number.

4.2 Working Drafts

All document identification codes are to include identification of the authoring group, ie. "SG2" for Study Group 2 or "SC" for Steering Committee, followed by an indication of WD for the document status, followed by an oblique and then the document number (N) and revision number (R). Document numbers will be given according to the following system:

Examples: SG2 (WD)/N21R5

SG3 (WD)/N7R3

SC/(WD)N1R2

Other authoring group codes might include "AH" for Ad Hoc Working Group or "WG" for Working Group.

4.3 Proposed Documents

Because documents at the Proposed Document Stage are being disseminated for public comment, the document code described above is to be modified with the addition of the letters "PD and version of the document posted" in parentheses (i.e., PD1, PD2, after the authoring group identifier.

Example: SC(PD3)/N1R3

4.4 Final Document

Once endorsed by the Steering Committee and signed off by the GHTF Chair, all GHTF documents are to be designated using the letters "GHTF", followed by an oblique and the authoring group identifier. This will then be followed by an oblique, the document number (N), the revision number (R), a colon and the current calendar year.

Examples: GHTF/SG2/N21:1999
GHTF/SG3/N7:1997

For security and to prevent unauthorized alteration, final documents should normally be published in PDF format, unless PDF is not appropriate. Any forms and related documents intended for downloading and use of the public may be posted in another format.

5. Maintenance of GHTF Documents

Due to the changing regulatory environment in which the GHTF operates, and the fact that GHTF documents are in the public domain, all GHTF documents are to be reviewed and revised every three years or, on an as-needed basis. The GHTF Steering Committee will consider at each face-to-face meeting the list of documents requiring review. Where revision is agreed to be undertaken, the GHTF Steering Committee will refer the revision to either a Study Group constituted for the purpose on a fixed scope basis, or to an Ad Hoc Working Group on a one-off basis. The contact person for the document indicated on the website should also be re-designated if needed.

Documents undergoing revision must receive Steering Committee endorsement and therefore, Study Group or Ad Hoc Working Group Chairs should indicate what changes have been made, by highlighting additions and deletions, when they submit a document for re-endorsement using the Document Transmittal Record (Annex F). For minor editorial changes, not involving substantive changes, agreement of the GHTF Chair is sufficient.

When re-published (and therefore re-posted on the GHTF website), amended documents must be designated as described above but with the inclusion of the text "(Edition X)" (where "X" represents the number of the current revision).

Example: GHTF/SG4/N10R2:1999 (Edition 2)
GHTF/SC/N3R2:2000 (Edition 3)

It should be noted that the original year in which the document was originally endorsed will change in the document identification code.

Example: GHTF/SC/N3R2:2000 (Edition 3)
GHTF/SC/N3R2:2001 (Edition 4)

6. Record-Keeping/ Information Archives

The Secretariat will maintain a listed inventory and actual texts of documents and Document Transmittal Records. The inventory will show the stage of development of each document, e.g., WD or PD, along with any relevant notes, e.g., the deadline for comment, etc. The Secretariat will maintain a master list of all GHTF documents.

The GHTF Secretariat will make an updated master list available at each GHTF Conference. In addition, the GHTF Secretariat has custodial responsibility for all hard-copy records passed on from previous and current Chair.

A searchable repository of all GHTF Final Documents and in-process Proposed Documents will also be maintained on the GHTF website.

7. Translation of GHTF guidance documents

In general, GHTF will:

(1) Make available on its website links to external sources of any translated versions of GHTF documents. Such links will be accompanied by a disclaimer stating that visitors are leaving the GHTF website and that GHTF is not responsible for other websites where translated documents may be available or for the quality of those documents.

(2) Where the GHTF Steering Committee is aware of such translated documents, it will encourage the producing party to include a statement, both on the website and in the document itself, to the effect that "This document has been translated from the original GHTF English version <GHTF document and revision numbers>, by <Institution or name of translator> on <date>. Where discrepancies exist between this document and the original English GHTF document they should be resolved in favor of the current original English GHTF document."

(3) As and when the Steering Committee becomes aware of documents translated by other parties, it may invite GHTF Study Group members, especially those involved in drafting the original English documents, and/or Steering Committee members, if fluent in the translated document language(s) to review them for accuracy. Significant discrepancies should be brought to the attention of the translating party.

8. GHTF-Related Presentations and Training

It is recognized that as the work of the GHTF progresses, those involved in Study Group, Ad Hoc Working Group or Steering Committee work may be called upon to do presentations or provide information on a part or parts of the GHTF's activities to their peers, trade association groups or regulatory authorities.

In all cases, the member being asked to do the presentation is asked to inform the GHTF Chair and/or GHTF Secretariat of the request. In the future, copies of slides used in these presentations may be made available to interested parties via the GHTF website.

When persons or groups organize a training event and claim to represent GHTF they shall seek prior consent from the GHTF Chair.

9. GHTF Logo

The GHTF has adopted the logo depicted on the front cover of this document. This logo should appear on all formal GHTF correspondence, reports, and the front cover of all GHTF documents, and should be displayed within the GHTF website.

The GHTF logo is not registered or trademarked in any way so its use by persons outside the GHTF is not impossible. Knowledge of such activity however, should therefore be reported to the GHTF Chair.

Annexures

ANNEX A

ANNEX A

Assignment of New Work

Stage 1 The Steering Committee considers the need for a new work item and where agreed,, allocates the work item to a Study Group (which may be established for the purpose) or an Ad Hoc Working Group. The GHTF Steering Committee may allocate a priority to each task.

SG or AHWG develops Working Draft

Stage 2 The Study Group or Ad Hoc Working Group develops Working Draft using input from appropriate interested parties.

Consultation on Working Drafts

Stage 3 After reaching internal consensus on the Working Draft, the Chair of the SG or AHWG invites its members to obtain comments with the aim of soliciting the broadest consultation appropriate without making the document publicly available. The Working Draft will not be posted on the website.

Advancement from Working Draft to Proposed Document

Stage 4 The Chair of the SG or AHWG forwards the Working Draft to the GHTF Chair for circulation to members of the Steering Committee using the Document Transmittal Record. The Steering Committee must receive the document at least eight weeks in advance of the next meeting to review it and make recommendations.

Consultation on Proposed Documents

Stage 5 Proposed Documents are posted on the website with a comment period of six months. Study Groups have six months to issue a revised document.

Advancement from Proposed Document to Final Document

Stage 6 The Chair of the SG or AHWG forwards the document to the GHTF

Chair using the Document Transmittal Record who circulates it to the Steering Committee for review. The Steering Committee must receive the document at least two months in advance of its next meeting in order to make recommendations. When consensus is achieved, the document can be signed off (cover sheet).

GHTF Document is published

Stage 7 The GHTF Chair posts document on the GHTF website for adoption and implementation.

ANNEX B

ANNEX B

Different types of GHTF documents*:

- Guidance documents
- Reference documents
- Status document
- Meeting minutes
- Summary of meetings
- Training documents

* The above described procedures apply foremost to GHTF guidance documents, the Steering Committee decides about the procedures applying to other types of documents.

Document Status Designations:

NWI	=	New Work Item
WD	=	Working Draft
PD	=	Proposed Document
FD	=	Final Document
FD (edition)	=	Edition of Final Document

ANNEX C

PROCEDURAL SHEET
FOR GUIDANCE DOCUMENT

Study Group N : Date of Last update:
Work item: **Reference :**

Stage	**Procedural steps**	**Check**
1.	**Assignment of new work item by the SC** Date of decision :	
2.	**Working draft development** Date of completion :	
3.	**Consultation on working draft** Date of completion :	
4.	**Working draft advances to proposed document** • WD forwarded by SG or AHWG chair to GHTF chair • GHTF chair circulates WD to SC members • Recommendation of SC to advance to PD Date of completion :	
5.	**Public consultation on proposed document** • PD posted on website by SG chair • Revised document issued by SG Date of completion :	
6.	**Proposed document advances to final document** • SG chair forwards revised PD to GHTF • GHTF chair forwards PD to SC members • SC issues a recommendation • SC recommends advancement to FD • SC issues another recommendation • SC chair signs the FD Date of completion :	
7.	**Final Document publication** • GHTF chair posts final document on website Date of completion :	

Latest update of the procedural sheet ……..

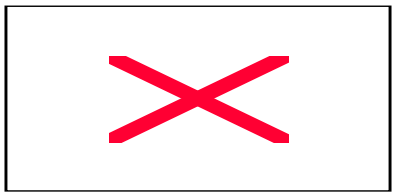
ANNEX D

FORMAT FOR GHTF NEW WORK ITEM (NWI)	
Title of the work item	
Purpose and rationale (including a reference to one or more of the goals in the GHTF Strategic Direction)	
Scope (including outline of issues to be addressed and opportunities for regulatory convergence)	
General Work Plan and timelines	
Proposed project leader	
Proposed sources of necessary expertise	
Relevant existing documents at GHTF and national level, as well as in international bodies.	

ANNEX E

ANNEX E

Cover Page For Final GHTF Documents



Title:

Authoring Group:

Endorsed by:

Date:

[Signature], GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

ANNEX F

ANNEX F

GHTF Steering Committee Document Transmittal Record	
From Study Group or AHWG:	To: GHTF Steering Committee
For consideration at Steering Committee meeting on (date):	
Document title:	
Document number and revision:	Date:
Reason: □ Proposed for approval for posting as Proposed Document for public comment (Proposed duration of comment period:) □ Proposed for approval for posting as Final Document □ Recommendations proposed for Steering Committee consideration □ Other (explain):	
Original approved New Work Item Proposal or mandate for this document (and date):	
Purpose: □ New document □ Periodic routine revision or update of previously released Final Document □ Other (explain):	
Document history (e.g., dates of previous PD, FD, or prior review by Steering Committee	
Revisions (if any) since previous review by Steering Committee and reasons:	
Points for specific consideration by Steering Committee (if any):	

Consequent changes required in other GHTF documents if this document is adopted (if any):
Remarks:
Steering Committee disposition: