

**REPORT OF THE SG1 MEETING HELD ON
9th to 12th MAY 2007 IN LOS ANGELES**

Attendees

Chair - Ginette Michaud
Vice-Chair - Benny Ons
Secretary - Alan Kent

North America

Mark Melkerson – FDA, USA
Nancy Shadeed - Health Canada
Brenda Murphy – MEDEC, Canada
Michael Gropp – AdvaMed, USA

Europe

Elke Lehmann – European Commission
Carl Wallroth – EUROM VI/EMIG
John Brennan – European Commission
Peter Linders – COCIR/EMIG

Asia/Australasia

Naoki Morooka – JFMDA, Japan
Shinichi Takae – MHLW, Japan
Mike Flood – TGA, Australia

Asian Harmonization Working Party

Daphne Yeh – Philips Medical, Chinese Taipei

Apologies

Alfred Kwek – Health Sciences Authority, Singapore

1 **Welcome to the meeting and introduction of delegates**

Ginette Michaud, Chair of SG1, welcomed SG1 members to the SG1 meeting. The meeting was held on the premises of the FDA District Office at Irvine, California.

The Chair reported that Cliff Spong had joined SG1 as a representative of Australian industry, although he has not been able to attend this particular meeting.

2 **Adoption of Agenda and discussion of procedures for this meeting**

The Agenda was agreed.

3 Review of the notes of the meeting held on 6th to 9th February in Kyoto, Japan (Document GHTF. SG1. N062 of 2 May 2007).

The meeting report was accepted after two corrections to the names of those who had volunteered to join the ad hoc sub-group on the definition of the term ‘manufacturer’ (Item 5 of the report).

4 Review of SG 1 accomplishments and work plan

Prior to the meeting, the Secretary had circulated the most recent version of the *Status of Active GHTF Study Group Work Programme* (SG1/N034R25) dated 2 May 2007. The document was noted.

The Secretary will update *Status of Active GHTF Study Group Work Programme* (SG1/N034) before the next meeting and reissue to members.

Action: Secretary

The Secretary reported progress as follows:-

- a) The revision to the STED document had been fast-tracked by the Steering Committee and endorsed as a Proposed Document for public review. Many comments had been received and will be discussed during this meeting.
- b) Two documents providing guidance on the classification and conformity assessment of IVD medical devices, respectively, had been forwarded to the Steering Committee for advancement as a Proposed Document for public comment.
- c) The SG1 communications database was shared with the Steering Committee (i.e. SG1(PD)/N061R1 GHTF Communications Database dated 19 March 2007). It has been updated to add contacts in South and Central America.
- d) Comments on *SG1(PD)/N44 (September 12, 2006): Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)* had been received and will be discussed during this meeting.

5 Progress of SG1(WD)/N055R3 *The Definition of the Term “Manufacturer” and Related Entities*

The Secretary had chaired a meeting of an ad hoc sub-group to discuss a draft document entitled *The Definition of the Term “Manufacturer” and Related Entities*. He reported that members of the sub-group included representatives from SGs 1, 3 & 4; additionally, written comments had been received from SG 2.

The meeting took place on the 8th May and all the comments received were discussed. The text of the document was modified to incorporate agreed changes.

The revised document will be circulated to members of the ad hoc expert group, to all GHTF Study Group Chairs and to members of SG1. Comments on this second draft should be sent to the Secretary using a “comments” template before

1 September 2007. Those reviewing the revised document are encouraged to discuss the document with their legal contacts.

Action: Members of SG1

Unless the comments received are trivial, there will be a second meeting of the expert sub-group in Washington, during October. Details will follow nearer that time.

Action: Secretary

6 Report on the Meeting of the Steering Committee.

The Chair reported on her attendance at the Steering Committee meeting that had taken place prior to SG1's meeting.

- a) SG1 had been congratulated on expanding its membership through the addition of two representatives of the AHWP.
- b) Ginette thanked the Steering Committee for fast-tracking SG1's Proposed Document on the STED.
- c) SG1's two documents concerning IVD medical device classification and conformity assessment, respectively, had been endorsed as Proposed Documents and will be posted on the GHTF Website for comment.
- d) SG1's communications database was supported by the Steering Committee and is likely to be used by other SGs in the course of time.
- e) The Steering Committee has decided to conduct a Retrospective Review of the work of the GHTF. Beth Peterson of Health Canada and the first Chair of the Steering Committee, has agreed to lead the review. Alan Kent has been asked to be a member of the review team.
- f) The Steering Committee is formulating a plan to provide guidance on combination products. This is at an early stage and any involvement of SG1 will emerge during the next few months.
- g) A paper is being prepared by a member of the Steering Committee to inform Study Groups of likely changes to European Directives. These may have relevance to SG1's future work.
- h) The Steering Committee will be making improvements to the GHTF website.
- i) The Steering Committee has formed an ad hoc working group to consider software either used with, or incorporated into medical devices. It is preparing a paper to provide Study Groups with specific recommendations on the subject. Carl Wallroth will be sending details on an issue he sees between some aspects of this work and an international standard on software, once the Steering Committee has circulated its document.

Action: Carl Wallroth

- j) The relationship between the work of ISO TC 212 Clinical Laboratory Testing and that of the IVDD sub-group was discussed. SG1's position will be developed by Carl, Benny and Nancy.

Action: Carl Wallroth, Benny Ons and Nancy Shadeed

- k) The Steering Committee had placed other actions on SG1. A list of these will be circulated after the meeting.

Action: Chair

7 Report from the SG1 IVDD Subgroup – Ms. Nancy Shadeed.

The sub-group has started work on their new work item (Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices), using the latest version of the STED as a template. Good progress has been made. It was agreed that Performance Evaluation will be part of this document and, probably, an Annex describing how Performance Evaluation studies should be undertaken. A link to the work of SG5 will have to be developed. The Chair asked Nancy to draft a document describing the contents of such an Appendix.

Action: Nancy Shadeed

The first joint meeting with SG5 was held on 10th May. It was a productive meeting. SG5 has agreed that the IVD sub-group will draft a parallel document on clinical evidence for IVDs for later discussion by SG5.

Action: Nancy Shadeed

8 Update on the Work of the AHWP

Daphne Yeh reported on the 6th Meeting of the AHWP Technical Committee in Hong Kong.

- a) "Shadow" Working Groups were formed to align with the work of:
- GHTF SG1;
 - GHTF SG1 IVDD sub-group;
 - GHTF SG2;
- and also a
- regulatory training group.
- b) During the meeting two SG1 documents were discussed; i.e. Definition of the Term 'Manufacturer' and the latest version of the STED. It was recognised that the revised STED had been influenced by the AHWP's document on the same subject (the CSTD).
- c) Minutes of the meeting will be posted on the AHWP website in the near future.

- 9 SG1/N011R20 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) of March 5, 2007: revision of proposed guideline.

This document has been subject to public review and over 120 comments have been received. These were discussed in turn by SG1 and the text of the document was modified as agreed.

The Vice-Chair agreed to make two changes to Figure 1 of the documents and send the revised diagram to the Secretary for incorporating into the document.

Action: Benny Ons

John Brennan agreed to change Appendix A of the document to align with the comment from JFMDA and ABHI (comments 116 and 119) and send the revised Appendix to the Secretary for incorporating into the document.

Action: John Brennan

Some editorial work will be completed after this meeting and the revised document will be circulated, first to the Chair and Vice-Chair and subsequently to SG1.

Action: Secretary

The consolidated list of comments, updated to indicate outcome will be circulated, first to the Chair and Vice-Chair and subsequently to SG1.

Action: Secretary

After a period for review by SG1, the document will be forwarded to the Steering Committee for endorsement as a Final Document. The October meeting in Washington will provide an opportunity to 'roll out' the STED to the AHWP and other interested parties.

Action: Chair

STED Implementation Status

The Chair asked different jurisdictions to report on the current status of the STED. Feedback was as follows:-

Canada – mixed messages from industry. Lack of clarity as to which RAs will accept the STED? The fact that the STED is not prescriptive regarding format/structure means that you require multiple STEDS rather than a single one across jurisdictions.

Australia – require an Australian version of the STED to be used. Need to build a level of trust between the reviewers and industry before wider goals are achieved.

Europe – once the revised version has been accepted it will be published as a Commission guidance document. If it is accepted in countries other than Founding Members it would be an incentive for industry.

USA – only 30 received - a disappointing number. Industry asks: what is the incentive to use it? The ‘devil you know’ approach predominates. The revisions to the STED might improve uptake. Within the FDA many reviewers do not understand it and have to be persuaded to accept a submission in that format. Michael Gropp – if it encouraged the use of electronic submissions rather than paper-based, it would have a better take-up.

Japan – current regulations require use of the Japanese version of the STED but this was based on the existing version rather than the upcoming revision. However, submission must be in Japanese which offsets the advantage to the manufacturer of having a single STED for world-wide use.

Factors to emerge from this part of the discussion were:–

- Providing an ‘incentive’ to manufacturers to use the STED; and
- Many of those responsible for the premarket review of a manufacturer’s documentation (STED, 510(k) etc.) have a poor understanding of QMS systems. Such reviewers in RAs and CABs would benefit from experience of QMS auditing.

10 Progress on SG1(PD)/N44 (October 3, 2006): Role of Standards in the Assessment of Medical Devices (revised)

Public comments on the version dated October 3, 2006 were discussed and incorporated where agreed. The list of comments was updated to show the outcome of the discussions.

A revised version of the document will be circulated to SG1 for any final comments with the hope that the document may then be sent to the Steering Committee for endorsement as a Final Document.

Action: Secretary and SG1

11 Registration of manufacturers and their medical devices by the Regulatory Authority: development plan

The Chair reported that Michael Gropp had agreed to write a first draft of guidance on this topic.

Action: Michael Gropp

Action: Secretary to send previous work proposal to Michael Gropp together with a GHTF formatted “template” for the work.

12 Document Priorities and Timetable

Six SG1 documents (two agreed during the most recent meeting of the Steering Committee) are posted on the GHTF web site as Final Documents:

- SG1/N012 *Role of Standards in the Assessment of Medical Devices* (18 November 1999)

- SG1/N29:2005 *Information Document Concerning the Definition of the Term “Medical Device”*
- SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*
- SG1/N43:2005 *Labelling for Medical Devices*
- SG1/N015:2006 *Principles of Medical Devices Classification*
- SG1/N040:2006 *Principles of Conformity Assessment for Medical Devices*

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	PRIORITY	TARGET FOR COMPLETION
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N011	Comments on the Proposed Document reviewed and text modified as appropriate.	1	Final Document 2007 / Q2
<i>Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012</i>	SG1/N044	Comments on the Proposed Document reviewed and text modified as appropriate.	1	Final Document 2007/ Q3
<i>Principles of Classification of In Vitro Diagnostic Medical Devices</i>	SG1/N045	Proposed Document endorsed by the Steering Committee for a four month posting on the GHTF website	1	Proposed document 2007 / Q2
<i>Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices</i>	SG1/N046	Proposed Document endorsed by the Steering Committee for a four month posting on the GHTF website	1	Proposed document 2007 / Q2

<i>The Definition of the Term “Manufacturer” and Related Entities</i>	SG1/N055	Working Draft revised & circulated for comment. Next review in October 2007	2	Proposed document 2008/Q2
<i>Registration of Manufacturers and their Medical Devices by the Regulatory Authority</i>		Drafting team identified. Work will start shortly	3	Proposed document 2008 / Q4
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance of IVD medical Devices</i>	SG1/N063	Working Draft under development	2	Proposed document 2008 / Q4

Future Role of GHTF Study Groups

The Chairman of the GHTF Steering Committee has asked each Study Group how it can further the goal of “approved once - accepted by all”. He acknowledged that many excellent GHTF guidance documents have been published but believed there had been little work to encourage implementation and their effective use.

During SG1’s discussion on this subject, the following points and suggestions were made:

- a) The GHTF is helping to build trust between members but we need to move towards similar legislation.
- b) One QMS audit should be sufficient for all regulatory regimes if trust is established.
- c) Do we know of the actual experience of implementing GHTF guidance, e.g. have the words written in guidance documents such as the STED resulted in similar interpretation by those who have read it?
- d) We should move from a maintenance phase to an implementation phase.
- e) RA/CAB reviewers would benefit from gaining experience of a QMS audit.
- f) SG1 should undertake a project to develop an “electronic STED”.

13 Date and place of next meeting

- 2007 GHTF Plenary, Washington DC: September 30 to October 2 with the conference on 3rd & 4th October. AdvaMed will hold its conference on 5th & 6th. It is possible that SG1 will meet before this at the same venue, possibly at the AdvaMed offices.

- Meeting in Bonn: Tuesday 5th to 8th February 2008, maybe in Bonn. **NOTE: these dates remain tentative.**

Action: Elke Lehmann

SUMMARY OF ACTIONS

For the Secretary

- To update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) before the next meeting and reissue to members.
- Consolidate comments on *The Definition of the Term “Manufacturer” and Related Entities* before the October meeting.
- Revise the STED and circulate first to the Chair and Vice-Chair and subsequently to SG1.
- Circulate the consolidated list of comments on the document *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*, with outcome, first to the Chair and Vice-Chair and subsequently to SG1.
- Revise the *Role of Standards* guidance document to SG1 together with the list of comments that have been discussed. Document.

For the Chair

- Circulate a list of the other actions the Steering Committee has placed onto SG1.
- After the revised STED has been reviewed by SG1, forward it to the Steering Committee for endorsement as a Final Document.

For the Vice-Chair

- Modify Figure 1 of the STED and send to the Secretary to be incorporated into the revised document.

For Nancy Shadeed

- Prepare a document describing the contents of the Annex the IVD sub-group will include in the IVDD STED which provides guidance on how Performance Evaluation studies should be undertaken.
- Progress the agreement with SG5 that the IVD sub-group will draft a parallel document on clinical evidence for IVDs for later discussion by SG5.

For Michael Gropp

- Prepare a first draft on guidance on ‘Registration of Manufacturers and their Medical Devices by the Regulatory Authority.

For John Brennan

- Modify Appendix A of the STED and send to the Secretary to be incorporated into the revised document.

Carl Wallroth, Benny Ons and Nancy Shadeed

- Jointly develop a position paper concerning the relationship between the work of ISO TC 212 Clinical Laboratory Testing and that of the IVDD sub-group.

Carl Wallroth

- Identify the issues between SG1 documents and the paper prepared by the Steering Committee's ad hoc working group on software that is either used with, or incorporated into medical devices.

Elke Lehmann

- Work with the Chair to organise the venue for SG1's meeting in February, 2008.

All Members of SG1

- Send comments on the revised version of the document entitled *The Definition of the Term "Manufacturer" and Related Entities* to the Secretary before 1 September 2007, consulting with legal experts where possible.
- Review the revised STED and send comments to the Chair.
- Review the revised *Role of Standards* guidance document and provide any final comments to the Secretary.