

**REPORT OF THE SG1 MEETING HELD ON
7/9th FEBRUARY 2007 IN KYOTO**

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

Alfred Kwek – Health Sciences Authority, Singapore

Observers

Tomomichi Nakazaki – JFMDA, Japan (7th/8th)

Kiyoshi Ikeda – PMDA, Japan

Hirofumi Koide – JACRI, Japan

Masahiko Hasumi – JFMDA, Japan

Hiroshi Ishikawa – JFMDA, Japan

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 Shimadzu Corporation in Kyoto, Japan. She thanked Naoki Morooka and his assistant for organising the event and providing facilities for the meeting and an invitation to dinner.

The Chair introduced two members of the Asian Harmonization Working Party (AHWP) who were joining SG1 as full participants in the ongoing development of harmonized guidelines, and to ensure smooth communication between the two organisations. This meeting followed a joint meeting between the AHWP,

represented by 15 members, and SG1. A separate report of that meeting will be issued.

The Chair reported that Fred Halverson, a long time representative of US industry at previous SG1 meetings, had retired from Medtronic. He had sent greetings to SG1 and wished it well in its future work. She wished to pay tribute to the considerable contribution he had made to the work of SG1 and wished him well in his retirement. These sentiments were endorsed by the members of SG1.

Action: Michael Gropp undertook to pass these sentiments back to Fred

2 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed.

3 Review of the notes of the meeting held in 23/6 October in Ghent (*Document GHTF. SG1. N060 of 6 October 2006*).

The Ghent meeting report was accepted after one correction since Ikeda-san did not attend the Ghent meeting. The record document needs modifying to that effect.

Action: Secretary

4 Review of Study Group 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/N034R24) dated 10 January 2007. The document was noted.

The Secretary will update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) before the next meeting and reissue to members.

Action: Secretary

The Secretary reported progress with the document that lists all the definitions that appear in GHTF Final and Proposed Documents. The work is being co-ordinated by Mr Hiroshi Ishikawa who presented a first draft to the Steering Committee at its last meeting. The Secretary, on behalf of SG1, has provided input to the various drafts of the document. There are a few definitions that differ between the various Study Groups; this will need to be resolved. It is intended that the same definitions will be used across all GHTF documents, unless there is a very good reason to deviate from this principle. SG1 will need to revise a few of its definitions (e.g. clinical investigation, where SG5 have developed a definition) at the appropriate time.

Document *SG1(PD)/N44 (September 12, 2006): Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)* was endorsed as a Proposed Document by the Steering Committee at its last meeting and placed on the GHTF web site for public comment. Comments may be submitted until 15 March 2007; they will be considered at SG1's next meeting in May.

Of the four new work item proposals submitted to the last Steering Committee, three were agreed. Namely:

- The definition of the term “manufacturer” and related entities (see next agenda item).
- Registration of Manufacturers and their Medical Devices by the Regulatory Authority
- Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.

The fourth one was not agreed but will be taken forward by the Steering Committee in a separate exercise using an ad-hoc group. Its title was:

- Procedure to determine the appropriate regulatory path for combination products and subsequent regulatory management of those products that have been deemed a medical device.

5 Discussion of SG1(WD)/N055R2 *The Definition of the Term “Manufacturer” and Related Entities*

The Secretary has completed a first draft of the document on the definition of a manufacturer and related entities and circulated it prior to this meeting together with a document describing issues that needed to be taken into consideration.

These two documents were discussed and modified as agreed. SG2 comments were considered and have been addressed.

A revised version of the definition guidance document (SG1(WD)/N055) and the associated background notes will be circulated to SG1 and sent to the other Study Groups shortly afterwards.

Action: Secretary

Issues to be flagged to those invited to comment:

- Does the definition provide a clear test of who has the regulatory responsibility for the device in a particular market?
- Do we need to retain the definition for “importer” as a related entity or is it self-evident?
- Are there other definitions that need to be included in the related entity section?
- What about manufacturers of custom made devices?
- The term ‘regulatory requirements’ includes both pre- and post-market requirements. Is it agreed that there is no need to spell this out?
- Is the term “fully refurbishing” (used in Note 1) appropriate?
- Do we need to incorporate text that explains the role of an OEM supplier? If so, could it be incorporated into the definition of ‘sub-contractor’?

SG1 members were asked to show the draft to their legal contacts and seek a view as to its adequacy. Comment will be sent to the Secretary using the template.

Action: Members of SG1

An expert sub-group will review the comments to take this matter forward, including representatives from the other Study Groups. The expert subgroup will meet on Tuesday May 8th in LA.

The sub-group will be chaired by the Secretary. Its membership will consist of a RA representative plus an Industry Association representative from each country/jurisdiction taken from the contributing Study Groups. Mark Melkerson will communicate with the other Study Groups and co-ordinate membership. (The following SG1 members showed an interest in being included: Mark Melkerson, John Brennan, Elke Lehmann, Mike Flood, Nancy Shadeed, Brenda Murphy, Michael Gropp, Morooka-san, Takae-san, AHWP).

Action: Mark Melkerson to co-ordinate.

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

Nancy Shadeed reported that a large number of comments on SG1(WD)/N045 *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification dated October 31, 2006* had been received, reviewed and incorporated where agreed. The list of comments tables has been updated to reflect the decisions made. It was agreed by SG1 this can be forwarded to the Steering Committee for advancement as a Proposed Document for Public Comment.

Action: Secretary

A covering note will be prepared to request input on unresolved issues.

Action: Nancy Shadeed

Nancy Shadeed reported that a large number of comments on SG1(WD)/N046 *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices dated October 31, 2006* had been received, reviewed and incorporated where agreed. The list of comments tables has been updated to reflect the decisions made. It was agreed by SG1 this can be forwarded to the Steering Committee for advancement as a Proposed Document for Public Comment.

Action: Secretary

The Chair congratulated the sub-group on their work.

The sub-group will start work on their new work item (Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices) in May, using the revised STED as a basis.

7 SG1/N011R17 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED): revision of proposed guideline.

Using the Excel spreadsheet developed during SG1's meeting in Ghent to identify a sequence of Section headings, SG1 revised the STED document. There is some further work required that will be completed as follows:-

Action: The Secretary will incorporate the revised text into the documents and forward to the Chair and Vice-Chair, together with the guidance from Canada and a list of changes made.

Action: The Chair and Vice-Chair will revise the document to incorporate information from the Canada guidance

Action: John Brennan to work on improving the EP checklist and forward to the Chair

Action: The revised document will be distributed to SG1 for comment

Action: The Chair will ask Dr Kessler, Chair of the Steering Committee, for an accelerated review before posting on the GHTF website for public comment

Action: Members of SG1 are requested to discuss with the members of the Steering Committee who represent them the request for an accelerated review of this document

8 SG1 Contact List

The Secretary circulated the latest version of the consolidated list of contacts prior to the meeting. The following actions were agreed.

Action: Mooroka-san to ensure Japanese Industry Associations are included

Action: Michael Gropp to ensure COPAC is included

Action: The Chair to ensure S. America RA's are included

Action: The Secretary to include International Standards Groups

Action: John Brennan to ensure European CA's are covered/included

Action – Alfred Kwek to ensure AHWP members are covered/included

9 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	PRIOR ITY	TARGET FOR COMPLETION
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N011	Proposed Document. Will be forwarded to the Steering Committee for “fast tracking”	1	Final Document 2007 / Q2
<i>Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012</i>	SG1/N044	Proposed document Public comments to be considered in May 2007	1	Final Document 2007/ Q3
<i>Principles of Classification of In Vitro Diagnostic Medical Devices</i>	SG1/N045	Proposed Document will be forwarded to the Steering Committee in March 2007 for endorsement and 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 will be forwarded to the Steering Committee in March 2007 for endorsement and posting on the GHTF website		Proposed document 2007 / Q2
<i>The Definition of the Term “Manufacturer” and Related Entities</i>	SG1/N055	Working Draft to be discussed by expert sub-group in May 2007	2	Proposed document 2008/Q4
<i>Registration of Manufacturers and their Medical devices by the Regulatory Authority</i>		Working Draft under development	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

10 Date and place of next meeting

- Joint meeting with other Study Groups: SG1 will meet from May 9th to 12th, 2007. The expert sub-group on definition of a manufacturer will meet on Tuesday 8th. The IVDD sub-group will meet on 7th/8th.
- 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. **NOTE: these dates are tentative.**
- Following SG1 meeting: 4 to 8th February 2008, maybe in Bonn. **NOTE: these dates are tentative.**

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.
- To circulate the revised WD for *The Definition of the Term “Manufacturer” and Related Entities* plus the associated background document and a comments template to SG1 and subsequently to other SGs.
- To forward *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*, a covering note and a list of comments considered to the Steering Committee for endorsement and posting on the GHTF website.
- To forward *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices* and a list of comments considered to the Steering Committee for endorsement and posting on the GHTF website.
- To incorporate the revised text into the STED guidance document and forward to the Chair and Vice-Chair, together with the guidance from Canada and a list of changes made.
- To include International Standards Groups on the SG1 contact list.

For the Chair

- To incorporate further changes into the STED guidance document and forward to SG1 members for comment.
- To ask Dr Kessler, Chair of the Steering Committee, for an accelerated review of the revised STED guidance document before posting on the GHTF website for public comment.
- To ensure S. America RA's are included on the SG1 contact list.

For the Vice-Chair

- With the Chair, to incorporate further changes into the STED guidance document.

For Nancy Shadeed

- To prepare a covering note to accompany *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification* when it is sent to the Steering Committee.

All SG1 Members

- To show the revised WD for *The Definition of the Term “Manufacturer” and Related Entities* to their legal contacts and seek a view as to its adequacy. Comment will be sent to the Secretary using the template.
- To comment on the revised version of the STED guidance document and discuss with the members of the Steering Committee who represent them the request for accelerated review.

For Michael Gropp

- To pass SG1's thanks to Fred Halverson for the contribution he had made to SG1's work.
- To ensure PAHO is included on the SG1 contact list.

For John Brennan

- To work on improving the EP checklist in the STED guidance and forward to the Chair.
- To ensure European CA's are covered/included on the SG1 contact list

For Mark Melkerson

- To contact the other SGs and co-ordinate the membership of the expert sub-group to discuss *The Definition of the Term "Manufacturer" and Related Entities*, in LA.

For Mooroka-san

- To ensure Japanese Industry Associations are included on the SG1 contact list.

For Alfred Kwek

- To ensure AHWP members are covered/included on the SG1 contact list.