

**REPORT OF THE SG1 MEETING HELD FROM 18<sup>th</sup> TO 21<sup>st</sup> MAY, 2010  
IN TOKYO, JAPAN**

**Attendees**

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

**North America**

Nancy Shadeed – Health Canada  
Brenda Murphy – MEDEC, Canada  
Michael Morton – AdvaMed, USA

**Europe**

Lennart Philipson – European Regulatory Authority  
Peter Bischoff-Everding – European Commission  
Peter Linders – COCIR/EMIG

**Australia/Japan**

Atsuchi Tamura – PMDA, Japan  
Naoki Morooka – JFMDA, Japan  
Tomomichi Nakazaki – JFMDA, Japan  
Kentaro Azuma – MHLW, Japan  
Gary Burgess – TGA, Australia  
Cliff Spong – MIAA, Australia

**AHWP**

Meshal Al Amri – Saudi Food and Drug Authority, KSA

**Apologies**

Mark Melkerson – FDA, USA  
Carl Wallroth – EUROM VI/EMIG  
Daphne Yeh – AHWP, Industry representative, Chinese Taipei/AHWP  
Huifan Bai – Health Sciences Authority, Singapore/AHWP  
Lindsay Tao – J&J, China/AHWP

**Observers**

Toshiyoshi Tominaga – PMDA, Japan  
Chieko Iijima – PMDA, Japan  
EriKo Yamazaki – PMDA, Japan  
Masaaki Tsukano - PMDA, Japan  
Yoko Ikeda – Nippon Beckton Dickinson, Japan  
Kazutoshi Yamagishi – Toshiba Medical Systems, Japan

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

Ginette Michaud, Chair of SG1, welcomed SG1 members and observers from Japan to the SG1 meeting. She thanked MHLW and the JFMDA for inviting SG1 to Tokyo and organising arrangements for the meeting.

Mr Toshiyoshi Tominaga made some welcoming remarks and acknowledged the valuable work of SG1 in the field of medical device regulation. He expressed the wholehearted support of the Japanese Ministry of Health to the work of the GHTF and wished SG1 every success in its work.

SG1 attendees and observers from Japan introduced themselves to the meeting.

Apologies of absence have been received from Mark Melkerson, Daphne Yeh, Huifan Bai and Lindsay Tao.

Although never a full member of SG1, Ginette wished to acknowledge David Racine's valuable contribution to SG1's work on registration & listing and on labelling.

Ginette reported that Carl Wallroth was standing down as a member of SG1 after being associated with its work for 20 years. She wished to acknowledge Carl's contribution to SG1 and wish him a long and happy retirement. SG1 showed its appreciation with a round of applause.

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

The Agenda was approved after some minor changes.

3 **Review of the report of the SG1 meeting held from 26<sup>th</sup> to 29<sup>th</sup> January, 2010 in Sao Paulo (Document GHTF. SG1. N79 of 29<sup>th</sup> January 2010) and review of action items**

The Sao Paulo Meeting Report was circulated prior to the meeting. It was approved without change.

Meeting actions were reviewed. All actions have been completed with one exception. Namely:

Benny Ons to raise with the Steering Committee the suggestion that the GHTF website should have a facility that allows interested parties to register and be informed automatically when new documents are posted on the website.

**Action: Benny Ons**

4 **Review of SG 1 accomplishments.**

The GHTF website has been updated regarding SG1 Meeting Reports, its membership and its Work Plan. The changes will be reviewed and further documents sent to the Secretariat as appropriate.

**Action: Secretary**

SG1's proposed document, *Labels & Instructions for Use for Medical Devices (SG1/N70R5)*, is posted on the GHTF website for comment. The Secretary used the Communications Database to inform interested parties of this fact. Any comments should be sent to the Secretary before 17<sup>th</sup> September 2010.

**Action: Members SG1**

The delay in progressing SG1 guidance on *Registration of Manufacturers and other Parties and Listing of Medical Devices* (SG1/N065) is on this meeting's agenda (see below).

The latest version of the Communications Database was circulated to SG1 prior to the meeting.

The *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan will be updated before the next meeting.

**Action: Secretary**

## 5 **Report from the In Vitro Diagnostic Medical Devices Subgroup (IVD MD Subgroup)**

Nancy Shadeed, Chair of the Sub-group reported on the meetings held in Bethesda during March, 2010. The main item on the agenda was reviewing 300 comments on the *STED of IVD Medical Devices* (GHTF/SG1(PD)/N063). Comments were discussed and the document modified as agreed. This version was circulated to SG1 prior to the meeting.

The Chair congratulated the IVD sub-group on its achievement.

SG1 reviewed the document and incorporated a few minor changes of an editorial nature. It was agreed by the representatives of the IVD sub-group in attendance at the SG1 meeting that the document be sent out to the subgroup immediately and that revisions may be discussed at its forthcoming meeting in June. Provided there is no major objection at that time, SG1 unanimously endorsed the document as a Final Document for submission to the Steering Committee. If there are objections within the IVD Subgroup to revisions introduced by SG1, these will be resolved by SG1 through e-mail communication prior to submitting the document to the Steering Committee.

**Action: Nancy Shadeed / Secretary**

Sections 5.3, 6.2.1 (re. 6.3), 6.2.2 and 7.0(b) were bookmarked for further consideration when the Final Document is subject to its first review in 5 years time.

**Action: Benny Ons**

It was agreed that when SG1 reviews the STED, it will incorporate improved text from GHTF/SG1/N063.

**Action: Secretary**

Also, at its last meeting, the IVD subgroup discussed the 2 documents entitled "*Concepts and Definitions- Clinical Evidence of IVD MD*" and "*Clinical Evidence for IVD MD – Clinical Utility and Performance Evaluation*" during its meeting in Bethesda. These documents have been circulated to Study Group 5 and the IVD subgroup and **will be discussed at the next Study Group 5 meeting in September 2010. Comments from SG5 will be considered at the December meeting of the IVD Subgroup along with any comments that the IVD subgroup members will submit.** Once the IVD subgroup has discussed these comments internally, the documents will be passed to Study Group 5.

Also the IVD subgroup briefly discussed the structure of the Essential Principles Document and the path forward with respect to separate sections for medical devices and IVD medical devices. A consensus could not be reached at the March meeting on the structure, therefore at the next

meeting in June, the subgroup will conduct an exercise to examine each essential principle and see if the existing language applies to both groups of devices.

The IVD subgroup has expressed concern that some of the text it has agreed is overridden by SG1. On the other hand, SG1 is concerned with the delays resulting from documents being passed back and forth between the subgroup and SG1. It was agreed that we require a procedural document to clarify the future handling of similar issues.

**Action: Nancy Shadeed**

## 6 Update on the Work of the Steering Committee

Benny Ons, SG1 Vice-Chair, reported that the Steering Committee met in May 2010. Items of particular interest to SG1 are:

- **Training** to be outsourced with an option for using non-profit organizations. During discussion, SG1 members had reservations regarding this proposal and will raise these with the relevant member of the Steering Committee. Benny is obtaining a copy of a key document on training dated 2008 which may answer some of the questions raised. He will circulate it to SG1.

**Action: Benny Ons**

SG1 will discuss this subject further at its meeting in October 2010.

**Action: Benny Ons**

- The discussion on **UDI** was disrupted by travel problems and will take place during June.
- Discussion on the **strategic direction of GHTF** has started with the aim of tabling a more detailed strategic plan for its November meeting that will be presented to the Heads of Agencies. SG1 members are invited to share their views with their representatives on the Steering Committee and with Benny.

**Action: SG1 members**

Also, other participants would wish to contribute to this review, e.g. Industry and Regulators from non-Founding Member jurisdictions.

**Action: Benny Ons**

- The Steering Committee **met with representatives of the AHWP** and invited them to join the GHTF as Regional Members. One matter of particular interest to SG1 is a comparison between the STED and the CSDT.
- The Steering Committee have yet to decide who will succeed Ginette as **Chair of SG1**. An announcement is expected
- Ginette made a presentation on the **work of SG1**.

**Action: Ginette to forward the final version of her presentation to the Secretary for circulation to SG1**

## 7 E-submissions and HL-7

Michael Morton presented the work of the SG1 subgroup on this subject. It was noted:

- The timeline appears unrealistic given the scope of work to be undertaken (Standard to be completed by January 2012). It appears to have been set to meet the needs of medicine regulators.
- The STED is very high level document compared with what is required by HL-7.
- The Steering Committee needs to be made aware of the size and expertise of the resource required if it wishes the GHTF to influence the outcome. Is the Steering Group willing to make the necessary commitment?

Michael will work with others to prepare a one page report that describes a potential GHTF-HL-7 collaboration and that draws the challenges and benefits of such a collaboration to the attention of the Steering Committee. Also, individual members of SG1 should communicate directly with their Steering Committee representatives.

**Action: Michael Morton and all members of SG1**

## 8 **Report from the Asian Harmonization Working Party**

Meshal Al Amri reported on progress within the AHWP after its recent meeting. Items of particular interest to SG1 are:

- Huifen Bai will replace Marianne Yap as both the Chair of TC Work Group 1 of the AHWP and as the AHWP member of SG1. She had a great deal of involvement in the writing of the CSDT.
- Singapore has mandated that the CSDT will be used for premarket submissions from May 2010.
- The AHWP has surveyed the use of key definitions throughout the AHWP jurisdictions and issued a document on the subject.
- The AHWP is considering setting up a permanent AHWP Secretariat located in Hong Kong.
- The AHWP has set as a priority the need to identify the differences between the CSDT and the STED and work to resolve them.
- The AHWP intends to provide comments on SG1 Proposed Documents.

Various AHWP documents of particular interest to SG1 will be circulated.

**Action: Secretary**

SG1 discussed the task of resolving the differences between the CSDT and the STED. It was agreed that a sub-group of SG1 should work with a sub-group of the AHWP to compare the two documents and suggest to SG1 and AHWP, respectively, how differences could be eliminated. This might result in a single document being adopted by the two organisations. The outcome of these discussions will be presented to SG1 by the end of August.

The SG1 members of the sub-group will be Alan Kent, Cliff Spong, Morooka-san, Peter Linders and Nancy Shadeed. Meshal Al Amri will ask the AHWP to nominate its membership by 8<sup>th</sup> June 2010 and send details to the Secretary.

**Action: Meshal Al Amri**

The group will be co-ordinated by Alan Kent who will contact members of the sub-group and suggest tasks to be completed. A report will be prepared by the end of August.

**Action: Secretary**

9 **Work on guidance document SG1/N065: Registration of Manufacturers and other Parties and Listing of Medical Devices**

When the Steering Committee reviewed this document it asked SG1 to consider inserting text into Sections 5.5 and 6.5 of the document that promoted the use of English in labelling, in addition to the national language. SG1 considered this request. The outcome of the discussion was that:

- There was no support to accept the proposal to modify the document.
- SG1 believes the current wording is already permissive and allows one or more languages, at the regulator's choice.
- In many countries there are regulations that require internal procedures to be in a national language.
- SG1 believed it was unreasonable to expect regulators operating an internal regulatory system to work in a language other than their own.
- The document will not be modified.

**Action: The Chair will report SG1's conclusions to the Steering Committee**

10 **Update on Latin American and Caribbean participation in SG1**

Little has changed since SG1's last meeting in Sao Paulo. Problems with the region taking up the seats offered to it by SG1 are:

- The appointment of participants who represent the region rather than individual countries requires consensus. This consensus is lacking.
- This has led to some individual countries asking whether they could participate but, to date, their participation has been declined by the SG1 Chair.
- Some LA countries have joined the AHWP as individual members.
- Some jurisdictions have budget & resource constraints, which would represent a barrier to participation.
- GHTF documents need to be translated if they are to be adopted widely in the region. Translations are needed for the most recent versions of SG1 documents.

- There is no mechanism or administrative structure to seek and consolidate comments on GHTF documents.

Various proposals were made to help resolve the problem by allowing some individual jurisdictions to join SG1 but there was no agreement. It was agreed to consider the outcome of the Steering Committee's deliberations on the same topic.

**Action: Vice-Chair**

11 **Revision of SG1/N029:2005 Information Document Concerning the Definition of the Term 'Medical Device'**

A list of suggested revisions to the document has been received. These were discussed in turn and the document modified as agreed.

The revised version of the document will be circulated to SG1, the IVD subgroup and other GHTF SGs. Any comments received during this process will be discussed during SG1's next meeting in October.

**Action: Secretary**

Two statements from the original document were deleted and will be considered when SG1 reviews the guidance on Conformity Assessment. They were:

'An accessory to a medical device should be subject to the same regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.) as a medical device. Some jurisdictions achieve this by incorporating 'accessory' into the definition of a medical device, while others achieve the same outcome by stating that although an accessory does not meet the definition of a medical device, it is subject to the same regulatory controls as the medical device itself.'

and

'Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device.'

**Action: Secretary**

SG1 discussed whether the reference to software was sufficient given the range of technologies that are available to "deliver" software to its associated hardware product. It was agreed to return to this subject when SG1 reviews the guidance on Conformity Assessment.

**Action: Secretary**

12 **Revision of SG1/N15:2006 Principles of Medical Devices Classification**

SG1 began its review of the document. The early sections were modified after discussion, some of which was stimulated by previously bookmarked comments and some by comments received through public consultation. The document was modified as agreed.

The revised version of the document will be circulated in preparation for SG1's next meeting in October at which time the review will continue.

**Action: Secretary**

It was agreed that **Section 5.0 General Principles** of the document needed to be rewritten. The revised text should provide a better description of the underlying basis for the rules. The new text will be drafted by Brenda Murphy, Cliff Spong, Nancy Shadeed and Michael Morton under the leadership of Tomomichi Nakazaki. The work should be completed by the end of August and e-mailed to the Secretary by the end of August.

**Action: Tomomichi Nakazaki**

The following definition was deleted from the document since the meaning is clear in the context of the paragraph where the phrase is used.

**Immediate danger:** A situation that is life threatening or may result in permanent impairment of a body function or permanent damage to a body structure; if no immediate preventative measure is taken.

### 13 Document Priorities and Timetable

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
<b>Study Group 1 – New Documents</b>				
<b>Registration of Manufacturers and other Parties and Listing of Medical Devices</b>	SG1/N065(PD)	Document submitted to SC for advancement as Final Document; SC requested that SG1 consider comment from EU industry; document returned to SG1 for resolution of comment; comment not accepted.	<b>1</b>	<b>Final Document 2010/Q3</b>
<b>SG1 IVD Medical Devices Subgroup – New Documents</b>				
<b>Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices [</b>	SG1/N063(PD)	Document has undergone minor revisions by SG1; final check of document by IVD Subgroup underway, after which document will be submitted to SC for advancement as a Final Document.	<b>1</b>	<b>Final Document 2010/Q4</b>



<b>Revision of SG1 Final Documents by SG1 and IVD MD Subgroup</b>				
<b>Label and Instructions for Use for Medical Devices</b>	<b>SG1/N070(PD)</b>	<b>Document posted as Proposed Document on GHTF website on April 26, 2010.</b>	<b>2</b>	<b>Proposed Document 2010/Q1</b>
<b>Essential Principles of Safety and Performance of Medical Devices</b>	<b>SG1/N068 Working draft</b>	<b>Document undergoing revision by IVD Medical Devices Subgroup.</b>	<b>2</b>	<b>Proposed Document 2010/Q4</b>
<b>Information Document Concerning the Definition of the Term “Medical Device” (revised)</b>	<b>SG1/N071</b>	<b>Document undergoing revision by GHTF Study Group 1.</b>	<b>3</b>	<b>Proposed Document 2010/Q4</b>
<b>Pending Revisions of SG1 Final Documents</b>				
<b>Principles of Medical Devices Classification</b>	<b>SG1/N015</b>	<b>Revision underway.</b>	<b>4</b>	<b>Proposed Document 2011/Q2</b>
<b>Principles of Conformity Assessment for Medical Devices</b>	<b>SG1/N040</b>	<b>Revision pending.</b>	<b>4</b>	<b>Proposed Document 2011/Q2</b>
<b>Possible New Work Items</b>				
<b>HL-7 and e-STED</b>		<b>SG1 Liaison group working with HL-7</b>	<b>?</b>	<b>?</b>

Other Work: SG1 and AHWP comparative review of STED and CSDT; report anticipated in August 2010.

#### 14 **SG1 Chair - interim succession planning**

The Chair, Ginette Michaud, announced her resignation from SG1. SG1 members expressed their deep regret and congratulated her on the many skills she had demonstrated in leading the Study Group over the past 5 years,

Ginette for her part thanked SG1 for its diligence, expertise and good humour. She believed much progress had been made and great commitment had been demonstrated in furthering the goals of GHTF. She acknowledged the support provided to her by Benny Ons, Nancy Shadeed and Alan Kent during her time as Chair.

The matter of appointing a new Chair had been discussed by the Steering Committee and an announcement should be made shortly. In the meantime, the Vice-Chair will lead SG1 and follow up on outstanding issues.

**Action: Benny Ons**

15 **Any Other Business**

None.

16 **Date and location of next meetings**

- Santa Rosa, California (2 hours North of San Francisco by road) from Tuesday 5<sup>th</sup> to 8<sup>th</sup> October 2010 at the invitation of Medtronic. Information on the hotel will be circulated after this meeting.

**Action - Secretary**

- Two further meeting dates were agreed; those of Feb 8<sup>th</sup> to 11<sup>th</sup> 2011 and June 7<sup>th</sup> to 10<sup>th</sup> 2011. One is likely to be in China and the other in Europe. Alan Kent undertook to contact the MHRA and ABHI to establish whether a meeting in London is feasible.

**Action - Secretary**

## SUMMARY OF ACTIONS

### For the Chair

- To report back to the Steering Committee the outcome of SG1's discussion of the proposed revision to the guidance document SG1/N065: *Registration of Manufacturers and other Parties and Listing of Medical Devices*.
- To forward the final version of her Steering Committee presentation to the Secretary for circulation to SG1.

### For the Secretary

- To send the GHTF Secretariat an updated SG1 Work Plan, Meeting Dates and Meeting Reports for posting on the GHTF website.
- To update *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- To incorporate improved text from GHTF/SG1/N063 when SG1 reviews the STED
- To co-ordinate the task of identifying the differences between the CSDT and the STED.
- To update the *Communications Database* and reissue to SG1 and meeting attendees.
- To circulate the four presentations made during the meeting to SG1 together with documents from the AHWP.
- To circulate the revised version of SG1/N029:2005 *Information Document Concerning the Definition of the Term 'Medical Device'* to SG1, the IVD subgroup and other GHTF SGs.
- To bookmark text to be discussed when SG1 reviews its guidance on Conformity Assessment.
- To circulate information on the Santa Rosa hotel
- To contact the MHRA and ABHI to establish whether a meeting in London during 2011 is feasible.

### For Nancy Shadeed, IVD Medical Devices Subgroup Chair

- To discuss editorial changes to the STED for IVD medical devices with the subgroup.
- To discuss draft document on *Essential Principles* with the IVD Subgroup and submit comments to the Chair and Secretary.
- To draft a procedural document to clarify the future handling of SG1 documents that incorporate text for IVD medical devices.

### **For Benny Ons**

- To raise with the Steering Committee the suggestion that the GHTF website should have a facility that allows interested parties to register and be informed automatically when new documents are posted on the website.
- To note that Sections 5.3, 6.2.1 (re. 6.3), 6.2.2 and 7.0(b) of the STED for IVD medical devices were bookmarked for further consideration when the Final Document is subject to its first review in 5 years time.
- To obtain a copy of a key Steering Committee document on training, dated 2008, and circulate to SG1.
- To lead SG1 and follow up on outstanding issues until a new Chair is appointed by the Steering Committee.

### **For SG1 Members**

- To note that the Proposed Document, *Labels & Instructions for Use for Medical Devices* (SG1/N70R5), is on the GHTF website and is available for comment.
- To share their views with their representatives on the Steering Committee regarding GHTF strategic direction.

### **For Michael Morton**

- To prepare for the Steering Committee a one page document on HL7 and Regulatory Product Submissions.

### **For Meshal Al Amri**

- To identify members of the AHWP to participate in the task of identifying the differences between the CSDT and the STED.

### **For Tomomichi Nakazaki**

- To co-ordinate an SG1 subgroup to revise Section 5.0 General Principles of *SG1/N15:2006 Principles of Medical Devices Classification*.