

**REPORT OF THE SG1 MEETING HELD FROM 20th TO 23rd JANUARY, 2009
IN SYDNEY, AUSTRALIA**

Attendees

Vice-Chair - Benny Ons

Secretary - Alan Kent

North America

Mark Melkerson – FDA, USA

Nancy Shadeed - Health Canada

Michael Morton - AdvaMed, USA

Europe

Peter Bischoff-Everding – European Commission

Peter Linders – COCIR/EMIG

Asia/Australasia

Mike Flood – TGA, Australia

Atsuchi Tamura – PMDA, Japan

Naoki Morooka – JFMDA, Japan

Tomomichi Nakazaki - JFMDA, Japan

Hiroshi Yaginuma – MHLW, Japan

Daphne Yeh – AHWP, Industry representative, Chinese Taipei

Cliff Spong - MTAA, Australia

Apologies

Chair - Ginette Michaud

Alfred Kwek – AHWP, Health Sciences Authority, Singapore

Carl Wallroth – EUROM VI/EMIG

Brenda Murphy – MEDEC, Canada

Observer

Shelley Tang – TGA, Australia

Rebecca Smith – J&J Australia

Jenny Forage – J&J Australia

1 Welcome to the meeting and introduction of delegates

Benny Ons, Vice-Chair of SG1, welcomed SG1 members to the SG1 meeting and explained that Ginette Michaud had flown back to the USA for personal reasons.

He thanked the J&J representatives for inviting SG1 to Sydney for the meeting. Unfortunately Marlene Valenti who had initiated the invitation could not attend this meeting and is standing down from SG1. Benny welcomed Michael Morton, who is replacing Marlene as the AdvaMed representative, to the meeting and requested the meeting report record SG1's thanks to Marlene for her contribution to its work.

The Vice-Chair provided apologies from four absent members of SG1 (see above).

The Vice-Chair described arrangements for the meeting.

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

The Agenda was agreed after adding an item to respond to the Steering Committee's questionnaire on UDI.

3 **Review of the report of the SG1 meeting held on the 14th to 17th October, 2008, in Ottawa (Document GHTF. SG1. N73 dated 18th October)**

The following actions have been completed:-

- An updated list of SG1 members has been sent to the GHTF website co-ordinator but the website has yet to be changed.
- The Chair met with Daphne Yeh prior to the meeting to discuss the situation in their region and the AHWP Work Plan.
- The Chair has discussed with other SG Chairs the proposal that each of the Study Groups offers two places (one regulator and one from industry) to the Latin American countries but awaits feedback from Study Group 2.

Action: Chair

- The Chair has submitted the names of Peter Linders and Mike Flood as available to join the Training Partnership ad-hoc Working Group. Cliff Spong offered to take part, too, and asked for his name to be submitted.

Action: Chair

- The revised document on *Registration of Manufacturers and other Parties and Listing of Medical Devices* has been forwarded to the Steering Committee with the recommendation that it is a Proposed Document for public comment. The document will be discussed by the Steering Committee during its February conference call.
- The revised document on *Essential Principles* and an updated list of comments was circulated to SG1 and subsequently to the IVD sub-group in order that they may consider the changes made (see item below for the outcome of sub-group's discussion).
- The revised document on *Labelling for Medical Devices* together with an updated list of comments was circulated to the IVD sub-group for it to consider the changes made (see item below for the outcome of sub-groups discussion).
- The IVD sub-group has tabled a Proposed Document entitled: *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices* for discussion at this meeting and endorsement by SG1.

4 **Review of SG 1 accomplishments.**

Prior to the meeting, the Secretary circulated the most recent version of the *Status of Active GHTF Study Group Work Programme* (SG1/N034R32) dated 6th December 2008.

The Secretary reported progress as follows:-

- a) Public comments have been received on SG1/N055R6 of 26th February, 2008 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* and will be discussed later in this meeting (see Item 8).
- b) SG1/N065R06 of 8th July, 2008: *Registration of Manufacturers and other Parties and Listing of Medical Devices* was discussed with other Study Groups on the 14th October. The document was modified accordingly and sent to Steering Committee as a Proposed Document for public comment.
- c) SG1/N068R01 *Essential Principles of Safety and Performance of Medical Devices* was discussed in Ottawa and a proposal for modification of the document was made for discussion at this meeting. It was discussed at the November meeting of the IVD sub-group. The sub-group's views will be considered later in this meeting (see Item 9).
- d) Most of the comments received on GHTF/SG1/N043:2005 *Labelling for Medical Devices*, were considered in Ottawa and the document modified as agreed. Outstanding comments and the views of IVD sub-group will be considered later in this meeting (see Item 11).
- e) Comments received for consideration when SG1 revises its guidance entitled *Information Document Concerning the Definition of the Term "Medical Device"*, have been consolidated and circulated to SG1. These will be discussed at a future meeting.

5 **Report from the In Vitro Diagnostic Medical Devices Subgroup**

The last meeting was held in November 2008. The sub-group's major work item was reviewing the remaining first stakeholder's comments on an IVD STED and modifying the guidance as agreed. The Proposed Document will be discussed later in this meeting. If SG1 agrees on it, it will be submitted for advancement to a proposed document which will go out for public comments.

At its meeting, the sub-group reviewed the changes made to the revised documents on *Labelling for Medical Devices* and on the *Essential Principles of Safety and Performance of Medical Devices* as they relate to IVD medical devices. The outcome of its deliberations will be discussed later in this meeting.

The sub-group is also working on drafting a document in collaboration with SG5 on clinical studies for IVD medical devices. SG5 will lead on the outcome of this work.

The next meeting of the sub-group will be held in June 2009. That meeting will be focused on the document on clinical studies and on the revised document on *Labelling for Medical Devices*. The IVD subgroup would be able to look at the document as it was finalized in SG1 in the May meeting in Toronto.

The subsequent meeting of the sub-group will be held in November 2009.

6 Report from the Asian Harmonization Working Party

Daphne Yeh updated the meeting on progress within the AHWP. She reported that China (Bao Ting Wang, General Director, Department of Medical Device, SFDA China) will chair the AHWP for the next 3 years with a representative from Indian Industry acting as Co-Chair (Saini Kulwant S. Saini, India Industry Rep, J&J India). New Chairs and Co-Chairs have been elected to the Technical Committee and all Working Groups. Alfred and Daphne have been elected Chair and Co-Chair, respectively, of the Technical committee. Daphne is the Co-Chair of WG1 with Alfred's colleague, Elaine, as Chair.

The AHWP consists of 16 jurisdictions namely China, Hong Kong, Chinese Taipei, Korea, Saudi Arabia and India together with the 10 ASEAN countries.

Work programmes and goals for the next 3 years, as suggested by the Working Group Chairs, are being finalised and adopted. They include updating the AHWP website and publishing a newsletter.

The Chinese SFDA is well organised and resourced which will be of great benefit to the AHWP as a whole. The International Co-operation Department of the SFDA will provide communication links to GHTF and other external organisations.

Singapore has announced its plans to introduce medical device regulations with a mandatory enforcement date during 2010.

The following actions were agreed:

- Daphne to provide the Secretary with the names of the elected Chairs and Co-Chairs so they may be added to the SG1 communications database.

Action: Daphne Yeh / Secretary

- SG1 will establish the status of the STED and inform the AHWP (see later item under AOB).

Action: Vice-Chair

- Daphne will recommend to WG1 of the AHWP that it considers the GHTF guidance document on *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* at the same time as it considers guidance on *Registration of Manufacturers and other Parties and Listing of Medical Devices*.

Action: Daphne Yeh

It was agreed that SG1 wished to strengthen its links with the AHWP and a discussion as to how this may be accomplished should take place between the Chair, Alfred and Daphne.

Action: Chair

7 Update on the Recent Steering Committee Meeting

In the absence of the Chair only a few items could be progressed, namely:-

- Global Regulatory Model - the submission of a revised draft document to the Steering Committee in December has been delayed.
- GMDN – progress has been made on new governance structure and business model for the Maintenance Agency.
- Retrospective Report – recently posted onto the GHTF website, together with a response from the Chairman of the Steering Committee.
- SG working procedures – an ad-hoc Group has been asked to make recommendations for process improvement – action ongoing.
- Glossary – posting onto the GHTF website of an updated glossary has been delayed.

8 **SG1(PD)/N055 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.**

The meeting reviewed the public comments received and modified the document as agreed. It will be sent to SG1 and other SGs for comment.

Action: Secretary

Subject to any comments received, it will be forwarded to the Steering Committee for endorsement as a Final Document.

Action: Chair

9 **Revision of GHTF/SG1/N41:2005 Essential Principles of Safety & Performance of Medical Devices**

After the previous meeting in Ottawa, the document was revised and sent first to SG1 and subsequently to the IVD sub-group. After discussion, the IVD sub-group asked for the changes to the layout of the document to be reversed with respect to placing principles relating only to IVD medical devices into a separate section, since it had insufficient time to review the relevant text and didn't want to delay progress on the document as a whole. After discussion, this suggestion was accepted by SG1. The IVD subgroup will start discussing this document in detail after completion of their current work to be ready with proposals for revising by the time this document will go to its next revision.

Action: Secretary to revise document as agreed

The revised document and the list of comments with their outcomes will be circulated both to SG1 and the ad-hoc Working Group on software. Subject to any comments made, these documents will be forwarded to the Steering Committee for endorsement as a Proposed Document for public comment.

Action: Secretary / Chair

10 **Responding to the Steering Committee's Questionnaire on UDI**

An ad-hoc working group of the GHTF Steering Committee has written a paper on Unique Device Identification (UDI). This group created a questionnaire to collect input of all stakeholders. After a wide ranging discussion on the subject, it was agreed SG1 would seek to answer only part of the questionnaire, concentrating on the possible contribution of UDI to patient safety, rather than on the philosophy and technology behind the initiative.

The table in Question # 5 was completed together with Section III (Question #15). The questionnaire will be sent to the Steering Committee.

Action: Secretary / Chair

11 **Revision of GHTF/SG1/N43:2005 Labelling for Medical Devices**

Comments on the guidance document were discussed and the document revised as agreed. The modified document will be circulated to SG1.

Action: Secretary

There was a long discussion on the definition of the term 'labelling'. Since no agreement was reached, a sub-group consisting of Mark Melkerson (leader), Hiroshi Yaginuma, Naoki Morooka, Michael Morton, Peter Bischoff-Everding and Cliff Spong will prepare a recommendation to resolve the issues raised prior to the next meeting in May.

Action: Mark Melkerson

During this discussion it was noted that the ISO 13485 definition is as follows:-

Labelling: Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or,

- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents.

NOTE: ISO 13485 does not incorporate definitions for 'label' or 'instructions for use'.

The following definitions were developed during the discussion but were unacceptable to some attendees.

Labelling: the label and instructions for use, providing information related to identification, technical description, and proper use of the medical device, excluding shipping documents.

Label: written, printed or graphic information either affixed to the medical device itself, or on the packaging of each unit or on the packaging of multiple devices.

Instructions for use: information provided by the manufacturer to inform the device user of the medical device's proper use and of any precautions to be taken.

The sub-group will consider Comment #17 also and recommend a definition for ‘Instructions for Use’.

Action: Mark Melkerson

There were different opinions as to whether the revised layout made the document easier to read and interpret. Most criticism was directed to the separation of a Section for “external packaging”.

SG1 members are asked to consider the following options before the May meeting.

Option 1: Have separate sections for the label, instructions for use, IVD medical devices, & external packaging (as in the version discussed in Sydney and circulated after the meeting).

Option 2: Have separate sections for the label, instructions for use & IVD medical devices but not for external packaging.

Option 3: Return to the original layout where the only separate section was for IVD medical devices (as in the 2005 Final Document).

Action: SG1

Three comments (#43, #45, #47) and the whole of Section 5.2.3 require the input of the IVD sub-group.

Action: Nancy Shadeed

Some comments were not discussed in either Ottawa or Sydney. These will be considered during the next meeting in Toronto as well as the resolution on the definition of labelling.

Action: Chair

12 Study Group 1 Communications Database

The Secretary reported that there had been no change since the Ottawa meeting.

The database will be revised to incorporate the names of the elected Chairs and Co-Chairs of the AHWP.

Action: Secretary

13 Document Priorities and Timetable

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
Study Group 1 – New Documents				

Definitions of the Terms Manufacturer Authorised Representative, Distributor and Importer.	SG1/N055	Public comments received on Proposed Document. These will be considered in Sydney.	1	Final Document 2009/Q4
Registration of Manufacturers and other Parties and Listing of Medical Devices	SG1/N065	Proposed document sent to Steering Committee. Public comment will follow.	1	Proposed Document 2009/Q1
SG1 IVD Medical Devices Subgroup – New Documents				
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.	SG1/N063	Proposed Document will be discussed by SG1 in Sydney.	1	Proposed Document 2009/Q2
Revision of SG1 Final Documents				
Essential Principles of Safety and Performance of Medical Devices (revised)	SG1/N069	Document modified as agreed in Ottawa. Views of IVD sub-group will be considered in Sydney.	2	Proposed Document 2009/Q4
Information Document Concerning the Definition of the Term “Medical Device” (revised)	SG1/N071	Comments received on GHTF/SG1/N029:2005. Not yet considered by SG1.	3	Proposed Document 2010/Q2
Labelling for Medical Devices (revised)	SG1/N070	Most comments received on GHTF/SG1/N043:2005 were considered in Ottawa and the document modified as agreed. Outstanding comments and views of IVD sub-group will be considered in Sydney.	3	Proposed Document 2009/Q4

14 Any Other Business

Combination products.

The following actions are carried over from the previous meeting:

- To circulate the Steering Committee’s ad-hoc group’s document on combination products.

Action: Secretary

- Individual SG1 members may respond to Michael Gropp directly regarding any further issues raised by his paper on combination products (providing the Chair, Vice-Chair and Secretary with a copy of any communication).

Action: SG1

Update on global implementation of the STED

Canada:- HC will introduce the STED using a similar technique to that used to implement an earlier ICH initiative. Part I of the legislation will be interpretive guidance and instructions on format; Part II will be the text of the STED. There will be ‘strong encouragement’ from HC for manufacturers to use the STED as an application document. The first step is to publish draft guidance for public comment.

EU:- the Commission has raised the issue with Member States and Notified Bodies; discussion continues. Some Member States are worried about the ‘snapshot in time’ concept rather than a ‘continually updated’ approach. When introduced it will be as a MEDDEV rather than a modification to the Directives. The Commission are likely to have a Workshop on the subject.

Japan:- already implemented and found to be a useful tool for reviewers. Progress is being made. In Japan, Class B, C, D devices requiring premarket submission (some Class B reviewed by NBs rather than RA) are the ones where the STED is being used.

USA:- decided to take all GHTF guidance documents through ‘good practice review’ but the STED is not on the documents to be reviewed during 2009. Use of the STED won’t be mandated through a regulation. Under current procedures, CDRH has just received its 50th STED which suggests poor ‘buy in’ from industry.

Australia:- not formally adopted but priorities lie elsewhere. It is the Government’s intent to adopt it through a guidance document but no decision has been made as to the timescale for implementation.

AHWP:- Singapore implementing CSTD from April 2009. Singapore has published a guidance document on the CSTD.

Action: Daphne to send a copy to the Secretary for circulation.

Membership of SG1

Mike Flood, the representative from TGA, announced that this was his last meeting and that he will leave SG1. The Vice-Chair thanked Mike for his valuable contributions to the work of SG1 over the past many years.

Mike’s replacement on SG1 is not known at the present time but will be announced shortly.

15 Date and place of next meeting

- SG1 will meet in Toronto in May from Sunday 10th to mid-day on Tuesday the 12th, as will the Steering Committee. The GHTF Conference will be held from Noon on Tuesday 12th May until 3:00 pm on Thursday the 14th. A training session will be held after the Conference.

- Brussels in 13 – 16th October, 2009, in an EU Commission building with support from Industry Associations – to be confirmed.

Action: Chair to provide further details at a later date

SUMMARY OF ACTIONS

For the Chair

- To progress discussions with other SG Chairs regarding the proposal that each of the Study Groups offer 2 places (one regulator and one from industry) to the Latin American countries.
- To offer the name of Cliff Spong as a contributor to the GHTF's Training Partnership ad-hoc Working Group.
- To discuss with Alfred and Daphne ways to strengthen the link between SG1 and the AHWP.
- To provide the Steering Committee with SG1's response to the UDI questionnaire.
- To continue reviewing the comments on GHTF/SG1/N43:2005 *Labelling for Medical Devices* during the next SG1 meeting in May.
- Subject to any comments received from other SGs, to send the revised guidance SG1(PD)/N055 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* to the Steering Committee for endorsement as a Final Document.
- Subject to any comments made, forward GHTF/SG1/N41:2005 *Essential Principles of Safety & Performance of Medical Devices* to the Steering Committee for endorsement as a Proposed Document for public comment.
- To provide SG1 with more information on the meeting in Brussels in 13 – 16th October, 2009 when such becomes available.

For the Secretary

- To update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- To revise GHTF/SG1/N43:2005 *Labelling for Medical Devices Labelling*, update list of comments and circulate to SG1.
- To revise SG1(PD)/N055 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* and send to SG1 and other SGs for comment.
- To revise GHTF/SG1/N41:2005 *Essential Principles of Safety & Performance of Medical Devices and circulate* to SG1 and the ad-hoc Working Group on software. Subject to any comments made, this document will be forwarded by the Chair to the Steering Committee for endorsement as a Proposed Document for public comment.
- To update the SG1 Communications Database.
- To circulate the Steering Committee's ad-hoc group's document on combination products.

For Mark Melkerson

- To lead an ad hoc sub-group to consider the definition of the terms ‘label’, ‘labelling’, ‘instructions for use’ and Comment #17 on the definition of ‘Instructions for Use’ and make recommendations for discussion at SG1’s next meeting in May.

For Daphne Yeh

- To provide the Secretary with the names of the elected Chairs and Co-Chairs of the AHWP so they may be added to the SG1 communications database.
- To report back to the AHWP the status of implementing the STED by Founder Members.
- To recommend to WG1 of the AHWP that it considers the GHTF guidance document on *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* at the same time as it considers guidance on *Registration of Manufacturers and other Parties and Listing of Medical Devices*.
- To send the Secretary Singapore’s guidance on the CSTD.