REPORT OF THE SG1 MEETING HELD FROM SEPTEMBER 30th TO OCTOBER 2nd, 2007 IN WASHINGTON DC

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 (for morning of September 30th)

Europe

John Brennan – European Commission
Elke Lehmann – European Regulatory Authority
Peter Linders – COCIR/EMIG

Asia/Australasia

Naoki Morooka – JFMDA, Japan
Shelley Tang – TGA, Australia
Cliff Spong - MIAA, Australia

Asian Harmonization Working Party

Alfred Kwek – Health Sciences Authority, Singapore

Apologies

Mike Flood – TGA, Australia
Daphne Yeh – Philips Medical, Chinese Taipei
Carl Wallroth – EUROM VI/EMIG
Kiyoshi Ikeda – PMDA, Japan
Hiroshi Yaginuma – MHLW, Japan

Observers

Tomomichi Nakazaki – JFMDA, Japan

(NOTE:- all the following attended & contributed during the Joint Meeting of SG1 with Latin American and Caribbean regulators and industry representatives on 2nd October; a subset of this group also observed other parts of SG1's meetings from 30 September to 2 October)
Gina Buendiaand – INVIMA, Columbia
Dulce Maria Martínez Pereira – CCEEM, Cuba
Agustín Iglesias Diez - ANMAT, Argentina
Emma Escandón Gonzalez – CENETEC, México
Maria Da Graça Hofmeister – ANVISA, Brazil
Mirtha Quiel - Ministeerio de Salud Pública, Panamá
Nancy Fernanadez - Instituto Salud Pública – ISP, Chile
Karen Malaga Vasquez – UNIMED, Bolivia

Maria Cristina Latorre - PAHO / WHO, Colombia
Nora Rodríguez – PAHO, Washington DC
Antonio Hernandez – PAHO / WHO, Washington DC
Adriana Pelza – Johnson & Johnson, MD & D
Sandra Dalberto – Johnson & Johnson, Brazil

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 members and the observers to the SG1 meeting. The meeting was held in Washington DC, USA and will be followed by the GHTF Conference and Plenary Session.

She noted that this was a welcome opportunity to exchange information with representatives of the Latin American and the Caribbean who will not only be observing SG1's meeting but also joining SG1 in a joint session. At the end of the conference there is a training session for Latin American attendees in which SG1 trainers will participate.

Attendees introduced themselves in turn to the group.

The Chair described arrangements for the day.

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 9th to 12th May, 2007 in Los Angeles, USA (*Document GHTF. SG1. N064*).

The meeting report was accepted without change.

The following two actions are carried over from the meeting in LA.

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.

Action: Carl Wallroth, Benny Ons and Nancy Shadeed

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.

Action: Carl Wallroth

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/N034R27) dated 17th September 2007 together with SG1's Work Plan of September 2007 . Both documents were reviewed.

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

Action: Secretary

The Secretary reported progress as follows:-

a) Further comments on the STED document 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 advanced as Proposed Documents for public comment. The comments received will be discussed at the IVD sub-group's next meeting (November 6 to 8, 2007) and agreed changes incorporated into the documents.

c) The SG1 communications database was shared with the Steering Committee (i.e. SG1(PD)/N061R1 GHTF Communications Database dated 19 March 2007) who recommended it to the other SGs.

Secretary: Copy database to other SG Chairs

d) SG/N044:2007 of August 28th, 2007: *Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)* had been sent to the Steering Committee for endorsement as a Final Document. If agreed, it will replace the previous version.

e) The Secretary will be chairing a second meeting of an ad hoc sub-group to discuss comments received on its draft document entitled *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer (*SG1(WD)/N055R4) on October 1st.

f) According to GHTF Operating Procedures, all Final Documents are subject to periodic review as follows:-

> *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, on an as-needed basis. The contact person for the document should also be re-designated if needed.*
>
> *Documents undergoing revision must receive Steering Committee endorsement and therefore, Study Group Chairs should indicate what changes have been made, by highlighting additions and deletions, when they submit a document for re-endorsement.*
>
> *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).

Three of SG1's documents fall into this category (Definition of Medical Device / Essential Principles / Labelling). It is proposed use SG1's Communication Database to ask for any suggestions as to where each document should be revised and, also, to review any comments that have been bookmarked for future review.

Action: Secretary

5 Discussion of SG1(WD)/N065R1 Registration of Manufacturers and Listing of Medical Devices

The Chair thanked Michael Gropp for preparing the first version of this new work item. The work was in response to a New Work Item Proposal dated November 2006.

Michael Gropp described the background to the document and his views on its role as the most basic form of regulatory control. He proposed that registration and listing be considered as different but related procedures. SG1 needs to agree these differences.

It was agreed that registration of manufacturers (and/or related entities) should not be used as a form of pre-market assessment, rather, it is an 'indication of presence' on the market. There was general consensus that the guidance should make it clear the RA is asking only for information on the medical devices available on a particular market and the organisation/s responsible for them.

The group considered whether Is the word "notification" is closer to the concept we wish to address rather than "registration"?

SG1's Conformity Assessment guidance includes the following text in Section 5.3:-

Registration of manufacturers and their medical devices by the Regulatory Authority
Registration of manufacturers and their medical devices by the RA is considered to be the most basic level of regulatory control of devices in the market. This registration system will identify the device/s and the party responsible for the device/s within the particular jurisdiction, thereby facilitating any regulatory activity.

Prior to placing a medical device on the market, the manufacturer, its local distributor or its Authorised Representative should provide the Regulatory Authority with the required information.

***The RA will maintain** the register.*

A new draft will be circulated together with a 'comments template'. Each line will be numbered for easy reference.

Action: Secretary

SG1 members will ask their legal contacts for a view on the draft document and send comments to the Chair, using the template, by December 31st, 2007.

Action: SG1

6 SG1(PD)/N011 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) – resolution of outstanding comments.

A list of the comments received had been circulated prior to this meeting and were discussed in turn. The decisions reached were recorded as outcomes on the lit of consolidated comments.

In addition, it was agreed that

- A division would be made after Section 5.0 that separates that part of the document that was 'background' from that which described the contents of the STED.
- That Section 9 start with a sub-heading "9.1 General" and incorporates the text: "It is recommended that the part of the STED that provides product verification and validation information should be arranged in a way that facilitates review by a RA / CAB and allows cross-reference to the EP checklist".
- When the conformity assessment guidance document is revised, consideration will be given to who 'signs off' the document on behalf of the manufacturer.

Action: Secretary to bookmark

The meeting discussed at length whether the STED is a pre-market "snapshot" of the device or a "living" document subject to continual updates that reflect post-market changes. During the discussion some members of SG1 changed their position. The SG1 consensus is that the STED should be considered to reflect a discrete point in time (a "snapshot") at which the device is placed on the market. Also, it became clear that while the technical documentation is the output of the manufacturer's QMS, the STED is outside such control. The document and the embedded Figure were modified to make it consistent with the "snapshot" approach.

Action: Secretary to modify Figure 1

Both the document and the list of consolidated comments relating to it were updated and will be circulated to SG1 when the agreed changes have been incorporated.

Action: Secretary

The opinion of the meeting was that the revised STED is now closely aligned with the AHWP CSDT.

The Secretary said that during the GHTF Retrospective Study that is ongoing currently, there were a number of comments emphasising the importance of the STED.

Action: SG1 to note

7 Joint meeting between Study Group 1 and Latin American regulators and industry representatives (LAHWP)

The Chair welcomed representatives of regulatory authorities and industry from South America and the Caribbean, as well as delegates from PAHO to a joint meeting with SG1. This is part of Study Group 1's outreach efforts.

After introductions, SG1 made presentations on its work.

- Ginette Michaud gave a presentation on the GHTF in general, its structure, working methods and output as well as the work of SG1.
- Alan Kent gave a presentation on SG1's Work Plan and his views on "Why Regulate?"
- Nancy Shadeed and Benny Ons gave a presentation on the work of the IVD Medical Devices sub-group.
- Alfred Kwek gave a presentation on the work of the Asian Harmonization Working Party.

Attendees from the Latin American counties made presentations on the situation in their region, as follows:-

- Agustín Iglesias Diez - ANMAT, Argentina
- Emma Escandón Gonzalez – CENETEC, México
- Maria Da Graça Hofmeister – ANVISA, Brazil
- Dulce Maria Martínez Pereira – CCEEM, Cuba
- Nancy Fernanadez - Instituto Salud Pública – ISP, Chile
- Mirtha Quiel - Ministeerio de Salud Pública, Panamá
- Karen Malaga Vasquez – UNIMED, Bolivia
- Gina Buendia – INVIMA, Columbia

Questions and answers were exchanged throughout the meeting. The Chair thanked the contributors for their informative presentations and invited the region to nominate 2 representatives to join SG1 as permanent participants, one from government and one from industry.

Action: Regulatory Authorities and industry representatives from South America and the Caribbean

A copy of each presentation will be e-mailed to attendees.

Action: Secretary

The Secretary has 6 spare copies of a document entitled "National Center for Health Technology Excellence" from the Ministry of Health in Mexico. Please contact the Secretary if you would like one of these.

Action: SG1

Additionally, it was noted:

- The countries that make up MERCOSUR (Brazil, Paraguay, Argentina & Uruguay) have committed to introducing the identical version of agreed "directives". In Year 2000 this extended to GHTF guidance documents.
- PAHO acts as a "facilitator". Its mandate is at a government level.
- The countries within the participating South American and Caribbean countries have a wide range of controls on medical devices reflecting their different histories and local industry base. Those implementing the GHTF Regulatory Model are doing so step-by-step.
- Only Chile appears to accept a role for Conformity Assessment Bodies.
- Some countries import all its medical devices (e.g. Panama).

8 Report from the Asian Harmonization Working Party

Alfred Kwek made a presentation to the Joint Meeting of SG1 and the Latin American Harmonization Working Party.

A copy of his presentation will be circulated.

Action: Secretary

9 Report from the SG1 IVDD Subgroup

Nancy Shadeed and Benny Ons made a presentation to the Joint Meeting of SG1 and the Latin American Harmonization Working Party.

A copy of their presentation will be circulated.

Action: Secretary

10 SG1(WD)/N055 The Definition of the Terms "Manufacturer", Authorised Representative, Distributor and Importer - progress report

The Secretary reported that 29 comments had been received on the version of the document dated May 8, 2007. All these were discussed at a second meeting of the ad hoc sub-group, held on October 1st. Good progress had been made and decisions were made on how to respond to each comment.

The guidance document will be updated and circulated to all Expert Subgroup members and GHTF Study Groups Chairs for circulation within their respective Study Groups. A comments template will be circulated with it. Comments are required by 31st December 2007.

Action: Secretary

11 Document Priorities and Timetable

Six SG1 documents 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:

DOCUMENT TITLE	REFERENCE	STATUS in SEPT 2007	PRIORITY	TARGET FOR COMPLETION
Study Group 1				
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance of Medical Devices (STED)	SG1/N011	Proposed Final Document, comments under review during Washington meeting	1	Final Document 2007 / Q4
Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012	SG1/N044	Proposed Final Document with Steering Committee for endorsement	1	Final Document 2007/ Q4
Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.	SG1/N055	Comments on 2nd draft will be discussed in Washington	2	Proposed document 2008/Q4
Registration of manufacturers and their medical devices by the Regulatory Authority	SG1/N065	Working draft developed for discussion in Washington	3	Proposed Document 2008/Q4
Final Documents for Revision				

Information Document Concerning the Definition of the Term "Medical Device"	GHTF/SG1/N 29:2005	Call for comments & suggested changes 2007/Q4	4	Proposed Document 2009/Q2
Essential Principles of Safety and Performance of Medical Devices	GHTF/SG1/N 041:2005	Call for comments & suggested changes 2007/Q4	4	Proposed Document 2009/Q2
Labelling for Medical Devices	GHTF/SG1/N 43:2005	Call for comments & suggested changes 2007/Q4	4	Proposed Document 2009/Q2
IVD Medical Devices Subgroup				
Principles of Classification of In Vitro Diagnostic Medical Devices	SG1/N045	Proposed Document posted on GHTF website on 14 May with comment period until 14 September 2007	1	Final document 2008 / Q2
Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices	SG1/N046	Proposed Document posted on GHTF website on 14 May with comment period until 14 September 2007	1	Final document 2008 / Q2
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.		First working draft in preparation	2	Proposed Document 2008/Q4

12 Date and place of next meeting

- From Tuesday 5th to 8th February 2008 in Bonn. This will be a joint SG meeting to allow further discussion on cross-Study Group matters, such as "Definition of the Term Manufacturer" and "Registration of Manufacturers and their Medical Devices". Revisions of existing documents will also begin at this meeting.

Action: Chair / Elke Lehmann

- Buenos Aires during May/June of 2008. To be confirmed

- **Action: Chair**

SUMMARY OF ACTIONS

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 copy SG1's communications database to other SG Chairs.
- Use SG1's Communication Database to ask for any suggestions as to where SG1's documents on Definition of Medical Device / Essential Principles / Labelling should be revised. Comments will be accepted up to mid-January.
- A new draft of SG1's guidance on Registration and Listing will be circulated to SG1 together with a 'comments template'. Each line will be numbered for easy reference.
- Update the STED, incorporating the changes agreed during the meeting, and circulate to SG1, via the Chair, together with the updated list of comments.
- Bookmark for the next revision of the conformity assessment guidance document the decision to consider who 'signs off' the document on behalf of the manufacturer.
- To e-mail a copy of each presentation made during the joint meeting of SG1 and the LAHWP to all attendees.
- To update the guidance on the definition of the term "manufacturer" to all interested parties together with a comments template.

For the Chair

- To liaise with Tim Missios, from Boston Scientific regarding the invitation for SG1 to meet in Buenos Aires in May/June 2008 and confirm arrangements to SG1.

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.

All Members of SG1

- To provide comments on SG1's guidance on Registration and Listing using the 'comments template' by 31 December 2007.
- To note that during the ongoing Retrospective Study that there were a number of comments emphasising the importance of the STED.
- To contact the Secretary if he/she requires a copy of a document entitled "National Center for Health Technology Excellence" from the Ministry of Health in Mexico.
- To provide comments to the Secretary on the updated guidance document on the definition of the term "manufacturer", using the comments table, by 31st December 2007.

Regulatory Authorities and industry representatives from South America and the Caribbean

- To nominate two representatives to join SG1 as permanent participants, one from government and one from industry.

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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.