**REPORT OF THE SG1 MEETING HELD FROM 26th TO 29th JANUARY, 2010
IN SAO PAULO, BRAZIL**

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

North America
David Racine – FDA, USA
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

Asia/Australasia
Atsuchi Tamura – PMDA, Japan
Naoki Morooka – JFMDA, Japan
Tomomichi Nakazaki – JFMDA, Japan
Kentaro Azuma – MHLW, Japan

AHWP
Meshal Al Amri – Saudi Food and Drug Authority, KSA

Apologies
Gary Burgess – TGA, Australia
Mark Melkerson – FDA, USA
Cliff Spong – MIAA, Australia
Carl Wallroth – EUROM VI/EMIG
Daphne Yeh – AHWP, Industry representative, Chinese Taipei
Marianne Yap – Health Sciences Authority, Singapore
Lindsay Tao – J&J, China

Observers
Dulce Maria Martinez Pereira – CCEEM, Cuba
Vivian Cardosa de Morais Oliveira – ANVISA, Brazil
Cristina Marios de Almeida – BD, Brazil
Adriana Belza – J&J, Latin America
Tim Missios – Boston Scientific, Americas & Asia Pacific
Sandra Moreira Dalberto – J&J Medical, Brazil
Lilian Garcia Orofino – Boston Scientific, Brazil
Elvia Padilla – BD, Mexico
Miguel Hernández – Commercial Service Officer, US Dept. of Commerce (Day 1)
Adriana Serrão - Vice-President of ABIMED
Fabiano Ribeiro de Lima – ABIMED, Philips, Brazil
Emilce Vicentin – ANMAT, Argentina

> Marcelo Artines – SQR Consulting, Brazil
> Humberto Olarte Cupas – MOH, Panama
> Simone Borges Diamantino – Philips, Brazil

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

Alexandre de Paula of ABIMED explained how the meeting and the dinner for SG1 will be organised.

Adriana Serrão, Vice-President of ABIMED welcomed SG1 to Sao Paulo.

Ginette Michaud, Chair of SG1, welcomed SG1 members and observers from Latin America and the Caribbean to the SG1 meeting. She thanked ABIMED for inviting SG1 to Sao Paulo and organising arrangements for the meeting.

The Chair welcomed Meshal Al Amri of the Saudi Food and Drug Authority to his first SG1 meeting as a representative of the AHWP regulators.

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

The Agenda was approved without change.

3 **Review of the report of the SG1 meeting held from 13th to 16th October, 2009 in Brussels, Belgium** *(Document GHTF. SG1. N76 of 13 December 2009)* **and review of action items**

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

Meeting actions were reviewed. All actions have been completed.

The Chair emphasised that SG1 wants Latin American countries to be involved in SG1 work and encouraged the region to develop mechanisms whereby it could nominate two regulators and two representatives of industry to represent the region at SG1 meetings.

4 **Review of SG 1 accomplishments.**

The Secretary used the Communications Database to inform interested parties that the IVD guidance document, SG1/N063 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices* was available for public comment.

The IVD sub-group will report on the outcome of their November meeting following this report.

The GHTF website has been updated regarding SG1 Meeting Reports, its membership and its Work Plan.

The Secretary provided the Steering Committee with personal comments on its draft document GHTF/AHWG(PD1)/N1R5: *GHTF Medical Device Regulatory Model.*

Progress with SG1 guidance on *Registration of Manufacturers and other Parties and Listing of Medical Devices* (SG1/N065) and on *Labels & Instructions for Use for Medical Devices* (SG1/N70R5) appear as agenda items for discussion later in this meeting.

The SG1 leadership held a teleconference with members of the AHWP to discuss how the two organisations could improve communication and co-operation. Further conference calls will be held in the year ahead.

The Secretary updated the Communications Database and has circulated it to SG1.

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 June and November 2009. She believed the sub-group was close to completing the task of providing SG5 with draft guidance on *Clinical Evidence for IVD medical devices*. It will provide 3 documents to SG5, each dealing with a different aspect of this subject.

Public comments have been received on the STED and these will be reviewed when the sub-groups next meets in March, 2010.

The sub-group reviewed SG1's draft guidance document SG1(PD)/N70 on labelling and sent their suggested edits to the Secretary. These will be discussed later in this meeting.

The Japanese delegation asked that a written report be provided prior to the meeting to help those whose national language is other than English.

Action: Nancy Shadeed

6 **Update on the Work of the Steering Committee**

Benny Ons, SG1 Vice-Chair, who has just joined the Steering Committee, reported that it met in November 2009. Items of interest to SG1 are:

- The GHTF Chair for the next 18 months is Larry Kelly of the TGA. The Chair then passes to Japan.

- The next face-to-face meeting of the Steering Committee is in May 2010.

- Significant comments have been received on the "Global Model" paper. The draft document will be revised.

- The GHTF procedures document on 'Roles and Responsibilities' is being updated.

- Three ad-hoc working groups have been disbanded; viz. those who worked on 'software', 'combination products' and 'maintenance'

- The discussion of combination products will be progressed at 'Heads of Agency' meetings rather than through the Steering Committee.

- The scope of the work of the ad-hoc working group considering 'regulatory change management' has been modified. Its Chair will be Garry Burgess of TGA.

- The strategic direction of GHTF will be discussed at the May meeting of the Steering Committee. The Chair suggested that members of SG1 should share their views with their representatives on the Steering Committee. Also, Benny would welcome the views of SG1 members as part of his preparation for the meeting.

Action: SG1 members

The Japanese delegation asked that a written report be provided prior to the meeting to help those whose national language is other than English.

Action: Benny Ons

7 **Report from the Asian Harmonization Working Party**

Meshal Al Amri reported:

- The AHWP has appointed four of its members to represent the region on SG1.

- In February, AHWP will be publishing a News Letter on its website.

- 400 delegates attended the AHWP annual meeting in Hong Kong that took place in November 2009.

- The AHWP intends to become a 'legal entity'. It is also writing governance and operational procedures.

- WG1 has a similar role within AHWP to SG1. It is undertaking a survey of existing regulations within the region.

- The Saudi FDA is much involved in the work of the AHWP.

- The 2010 annual meeting of the AHWP will be held in the Kingdom of Saudi Arabia in December.

The Chair attended the AHWP meeting in Hong Kong and was optimistic about the ongoing and future co-operation between GHTF and AHWP.

8   Report on Latin America and the Caribbean

Representatives of the Latin American (LA) and Caribbean jurisdictions made four presentations to SG1. The subjects covered were Regulations in Brazil, Regulations in Argentina, Regulations in Cuba and an overview of the region from an industry perspective. The presentations will be circulated and posted on the SG1 webpage after the meeting.

Action: Secretary

The Chair thanked each presenter (Vivian Oliveira, Emilce Vicentin, Dulce Maria Martinez Pereira and Elvia Padia) for their informative presentations that improved SG1's understanding of the region.

In response to questions, the following further information emerged:

- Brazilian GMP requirements are harmonized with those of the FDA rather than to ISO13485.

- Brazil undertakes overseas GMP audits using its own auditors at 2 year intervals. The Brazilian authority might use third party auditors in the future. They undertook 40 audits in 2008.

- Brazilian companies hold the requisite licenses. Where the manufacturer has multiple distributors, each must have a license.

- Cuba – the CCEEM has published a book on medical device regulation. It is written in Spanish and English.

- Argentina is part of MERCOSUR which has common definitions within its regulations.

- Argentina asks for manufacturers to submit premarket product submissions using the STED. This has caused them no problem. Their requirements are based on a 1999 draft of the STED rather than the Final Document.

- The ECRI code is used in Argentina rather than the GMDN.

- Mexican RAs were unable to attend the meeting at the last moment due to the work involved in launching a new registration and listing system. They sent their apologies. The register it is replacing had 45,000 entries, most of which are Class I devices. Their register incorporates additional information on each device rather than being a "simple" registration and listing database.

The Secretary will circulate the presentations.

Action: Secretary

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

After the last meeting in Brussels, the draft document was revised to incorporate the changes agreed at that meeting. The new draft was circulated to those attending this meeting (dated January 7, 2010). To focus discussion, outstanding comments have been incorporated into a

table that was circulated prior to the meeting (dated 7 January 2010) with an indication of which require further discussion by SG1.

The document was reviewed and further changes incorporated. The only subject that required extensive discussion was the need (or not) to provide information on the location of manufacturing sites. Eventually consensus was reached and a footnote was added to Section 6.5.1.

SG1 agreed that a 'clean' version of the guidance document will be sent to the Steering Committee with a request that it be endorsed as a Final Document and posted on the GHTF website.

Action: Chair

This version with an updated table of consolidated comments, with outcomes, will be circulated to meeting attendees.

Action: Secretary

10 **Revision of GHTF/SG1/N43:2005 Labelling for Medical Devices and its replacement with SG1/N70R6**

Prior to the meeting a further version of the guidance document was circulated (SG1(PD)/N70R6 dated Jan 8, 2010). The Chair explained that it had been subject to a large number of changes due to the need to incorporate:

- the changes agreed in Brussels; and

- the changes requested by the IVD sub-group.

The most significant changes to the text have been highlighting throughout the document.

Further more, late comments were received from the AHWP and from the Australian Industry Association. These have been incorporated into a single table.

SG1, with input from Latin American and Caribbean observers, reviewed the modified document and considered the latest comments from the AHWP and from the Australian Industry Association. As a result further changes to the text were made.

It was decided that the Steering Committee's draft document on UDI was at too early a stage to allow SG1's guidance document to be modified to take account of UDI. However, there would be an opportunity to do this after the public comment stage.

SG1 agreed that a revised version of the guidance document was complete and that it will be sent to the Steering Committee with a request that it be endorsed as a Proposed Document and posted on the GHTF website for public consultation.

Action: Chair

This version with an updated table of consolidated comments, with outcomes, will be circulated to meeting attendees.

Action: Secretary

11 **Discussion of comments on GHTF/AH(PD1)N2:R1** *Unique Device Identification (UDI)* *System***.**

The Steering Committee draft document on UDI was discussed. The following points were made by individual meeting participants:

- Industry's primary goal is to encourage regulators to adopt a single, harmonized approach globally.   This was the FDA's goal, too. SG1 believed that the involvement of the GHTF in the work offered the best opportunity of achieving this end.

- The relationship between UDI, SG1 documents and with the GHTF Global Regulatory Model is unclear. Compatibility does not seem to have been considered in writing GHTF/AH(PD1)N2:R1. SG1 is concerned that UDI is being considered in isolation from the work of the GHTF Study Groups.

- The first priority is to agree on the technology and the information to be incorporated into UDI. It is believed that if healthcare facilities see this has happened, they will purchase the necessary 'scanners' and thereby provide device traceability within their facilities.

- The team working on this project must include experts who have worked with large databases otherwise the project will fail. Incorporating a large amount of data onto the UDI (as may be the case in the EU) is a recipe for failure. Instead the UDI team should specify the absolute minimum of data.

- Will there be a single, global database?

- SG1 guidance on Registration & Listing may need to be modified to accommodate UDI. What will be the interface be between UDI and the Registration and Listing database? In some jurisdictions the Registration and Listing database is accessible to the public.

- There is a concern that the UDI project might divert resources from GHTF.

Those comments made by SG1 prior to the meeting that have identified overlap between SG1 documents and the UDI draft will be sent to the Steering Committee separately from those that apply to other aspects of the document.

Action: Chair

12 **E-submissions and HL-7**

The Chair reported that SG1 has been asked by the Steering Committee to provide liaison between HL7 (an independent standard writing organisation) and the GHTF. HL7 is writing a standard to allow manufacturers to submit premarket conformity assessment data to the RA electronically. While the pharmaceutical industry and its regulators have been involved in the work, medical device experts have not been involved to any great extent.

Michael Morton gave a presentation on his company's knowledge of the progress made.

The STED would appear to be a vehicle for structuring a Regulated Product Submission (RPS) from a medical device company.

A number of those present volunteered to find out more and monitor progress with e-submissions. They are Tomomichi Nakazaki, Tim Missios and Peter Linders. Michael Morton will coordinate the activity.

Action: Michael Morton

Meshal Al Amri will ask the AHWP whether they want to be involved.

Action: Meshal Al Amri

The Chair will ask the Steering Committee what they expect of SG1 given that they have not provided it with a new item of work.

Action: Chair

Michael's presentation will be circulated.

Action: Secretary

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

A list of suggested revisions to the document have been received. Discussion of them commenced and it was decided to incorporate a definition of IVD Medical device into the document.

Discussion will continue at SG1's next meeting in May.

14 **Study Group 1 Contacts Database - progress report**

The Secretary reported that he had received new data to be included into the Contacts Database. He would issue a new version shortly.

Action: Secretary

It was suggested 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. The Vice-Chair undertook to raise that suggestion with the Steering Committee.

Action: Benny Ons

15 <u>**Document Priorities and Timetable**</u>

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
Study Group 1 – New Documents				
Registration of Manufacturers and other Parties and Listing of Medical Devices.	**SG1/N065(PD)**	**Feb 2010 - proposed Final Document forwarded to the Steering Committee**	**1**	**Final Document 2010/Q3**
SG1 IVD Medical Devices Subgroup – New Documents				
Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices.	**SG1/N063(PD)**	**Public consultation ended Jan 7, 2010; resolution of public comments pending.**	**1**	**Final Document 2010/Q4**
Revision of SG1 Final Documents by SG1 and IVD MD Subgroup				
Label and Instructions for Use for Medical Devices.	**SG1/N070 Working draft**	**Feb 2010 - proposed Document forwarded to the Steering Committee for posting on the GHTF website.**	**2**	**Proposed Document 2010/Q1**
Essential Principles of Safety and Performance of Medical Devices.	**SG1/N068 Working draft**	**Document awaiting review by IVD Medical Devices Subgroup.**	**2**	**Proposed Document 2010/Q4**
Information Document Concerning the Definition of the Term "Medical Device" (revised).	**SG1/N071**	**Discussion of the comments received underway and will continue in May 2010.**	**3**	**Proposed Document 2010/Q4**
Pending Revisions of SG1 Final Documents				

Principles of Medical Devices Classification.	**SG1/N015**	**Informal consultation completed via SG1 Communications Database; awaiting AHWP input; revision pending.**	**4**	
Principles of Conformity Assessment for Medical Devices.	**SG1/N040**	**Informal consultation completed via SG1 Communications Database; awaiting AHWP input; revision pending.**	**4**	

16 **Any Other Business**

None.

17 **Date and location of next meetings**

- 18th to 21st May, 2010 in central Tokyo at the invitation of the MHLW. Further information will be provided when it becomes available.

Action: Chair and MHLW

- Santa Rosa, California (2 hours North of San Francisco by road) from Tuesday 5th to 8th October 2010 at the invitation of Medtronic.

SUMMARY OF ACTIONS

For the Chair

- To forward the guidance document on *Medical Device Labels and Instructions for Use* to the Steering Committee as a Proposed Document for endorsement and posting on the GHTF website for public comment.

- To forward the guidance document on *Registration and Listing* to the Steering Committee as a Final Document for endorsement and posting on the GHTF website.

- To forward comments from individual SG1 members on the UDI Ad Hoc Working Group's draft document on UDI.

- To ascertain the Steering Committees expectation of SG1 with regard to its liaison with HL7.

- To provide SG1 with information on the next meeting to be held in Tokyo when such becomes available.

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 prepare the guidance document on *Medical Device Labels and Instructions for Use* as a Proposed Document and forward it to the Chair and, together with an updated list of consolidated comments, to meeting attendees.

- To prepare the guidance document on *Registration and Listing* as a Final Document and forward it to the Chair and, together with an updated list of consolidated comments, to meeting attendees.

- To update the *Communications Database* and reissue to SG1 and meeting attendees.

- To circulate the four presentations made during the meeting to all attendees and submit them to the GHTF Secretariat for posting on the SG1 meeting reports webpage.

For Nancy Shadeed, IVD Medical Devices Subgroup Chair

- To discuss draft document on *Essential Principles* with the IVD Subgroup and submit comments to the Chair and Secretary.

- To use best endeavours to provide SG1 with a written report on the IVD Subgroup prior to each meeting to help those whose national language is other than English.

For Benny Ons

- To use best endeavours to provide SG1 with a written report on the Steering Committee prior to each meeting to help those whose national language is other than English.

- 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.

For SG1 Members

- To share their views with their representatives on the Steering Committee regarding GHTF strategic direction. Also, Benny would welcome the views of SG1 members as part of his preparation for the meeting.

For Michael Morton

- To lead and coordinate SG1's liaison activities with HL7.

For Meshal Al Amri

- To ask the AHWP whether they want to be involved in SG1's work on e-submissions and HL7.