REPORT OF THE SG1 MEETING HELD FROM 10th TO 12th MAY, 2009 IN TORONTO, ONTARIO, CANADA

Attendees

Chair - Ginette Michaud
Vice-Chair - Benny Ons

North America
Mark Melkerson – FDA, USA
Maria Carballo – Health Canada
Michael Morton - AdvaMed, USA
Brenda Murphy – MEDEC, Canada

Europe
Peter Bischoff-Everding – European Commission
Lennart Philipson – European Commission
Peter Linders – COCIR/EMIG
Carl Wallroth – EUROM VI/EMIG

Asia/Australasia
Gary Burgess – TGA, Australia
Cliff Spong - MTAA, Australia

Apologies
Secretary - Alan Kent
Nancy Shadeed - Health Canada
Hiroshi Yaginuma – MHLW, Japan
Atsuchi Tamura – PMDA, Japan
Naoki Morooka – JFMDA, Japan
Tomomichi Nakazaki - JFMDA, Japan
Alfred Kwek – AHWP, Health Sciences Authority, Singapore
Daphne Yeh – AHWP, Industry representative, Chinese Taipei

Observers
Lilian Orofino – Boston Scientific Latin America
Erica Treyillo – Johnson & Johnson Latin America
Sandra Dalberto – Johnson & Johnson Latin America
Adriana Belza – Johnson & Johnson Latin America
Elvia Padilla – BD Latin America

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 members to the SG1 meeting and welcomed the new members from EU and Australian regulators to SG1. Lennart Philipson is replacing Elke Lehman for European regulators and Gary Burgess is replacing Mike Flood for the Australian regulators.

The Chair provided apologies for the absent members and explained that unfortunately the Japanese delegation is not attending the meeting due to the H1N1 Influenza outbreak. The Chair

explained that, in view of these extraordinary circumstances, modifications to documents and all decisions from the Toronto meeting will be submitted to the Japanese delegation for their review prior to making any final decisions.

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

The Agenda was approved.

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*)**

Meeting minutes were accepted after adding the discussions related to the SG1/N063 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices:
"SG 1 reviewed the document tabled by the IVD subgroup. SG1 agreed to have this document submitted to the Steering Committee for advancement as a Proposed Document''.

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* and the *SG1 Work Plan* of April 2009.

The Secretary reported SG1 guidelines in need of periodic review/revision as follows:

- GHTF/SG1/N15:2006 Principles of Medical Devices Classification, 31 August 2006, 27 pages.
- GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices, Note: Discrepancy Between GHTF/SG1/ N040:2006 and GHTF/SG1/ N011:2008, 31 August 2006, 16 pages.

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

The next meeting of the IVD Medical Devices Sub-group will be held in June 2009. That meeting will be focused on the development of a guideline on clinical evidence for IVD medical devices, work that the IVD subgroup is undertaking on behalf of SG5.

Also, if time allows, the IVD Subgroup will discuss the revised document on *Labelling for Medical Devices*, however it is anticipated that this discussion may be postponed to the November meeting.

The subsequent meeting of the sub-group will be held in November 2009 in San Jose, California.

Comments on the STED for IVD medical devices are expected in the second half of 2009. Therefore, discussions on the comments will be postponed until the spring meeting of the IVD subgroup.

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

- The changes to the structure and management of the AHWP were documented in the Sydney Meeting Report (GHTF.SG1.N074 of 10 March 2009).

- A proposal to ask the AHWP to undertake the first review of two SG1 documents that are due for review (dealing with the classification and conformity assessment of medical devices, respectively) will be pursued.

- WG1 of AHWP is surveying its members for their definition of the term 'manufacturer', and it is planning on undertaking a similar survey for 'registration and listing'.

7 **Discussion of Medical Device Regulations within the Latin America and Caribbean Region**

Representatives from the region made a presentation and updated SG1 on progress since its last discussion of this topic.

GHTF 2007-2010 action plan

Goal – Currently do not use GHTF Guidance Documents in full as established in Resolution CD42.R10 on medical devices.

Goal – Expansion

- Involvement in other organizations: LA delegates in SG1, pending for the rest of the SG. How can we formalize the invitation of SG1 to ensure industry and regulator representatives are appointed?
- Increase public availability of procedures and documents:
- Current challenges: Version control & Translation
- Development and implementation of GHTF training plan
- APEC, GHTF sponsored trainings for countries with emerging or revised regulations coordinated by the Dept of Commerce

Training needs

- Design concept and quality systems vs GMP
- Devices where manufacturing steps are performed in different locations: Question raised: why inspect them all?
- Component approach vs raw materials

Accepting SG1's invitation for representatives from LA industry and regulators to participate in its meetings

- GHTF activities are understood by the regulatory community but not the industry upper management. This results in poor support to RA professionals wishing to participate.
- This results in a significant challenge to the LA region to appoint representatives to participate in the work.

Note: COCIR is encouraging industry in 'developing jurisdictions' to open local offices in their region.

Manufacturers and related entities

The concept of the use of a device being that "intended by the manufacturer" is not widespread in Latin American region

Breast implants will be considered a MD regardless of whether they are intended for cosmetic or other use.

Spare parts – some jurisdictions want to regulate spare parts. Question raised: Are spare parts medical devices?

Name of the "real manufacturer" -- increasing requirement in some jurisdictions to label the product as:

- manufactured by xxx for xxx (Mexico);
- Country of origin (Mexico);
- Importer's name and registration number.

Efforts against counterfeiting, initiatives that tend to ensure original seals are not broken.

Mexico

- Main obstacles in the re-registration process;
- Delay of nearly three years in providing guidance;
- Zip code changes from 5 digit to 9 digit stopped at the border.

Venezuela

- Renewal of registrations tied to provision of valid Certificates for Foreign Government (CFG) and Certificate of Free Sale (CFS);
- Samples required for testing.

Ecuador

- Sourcing country to be declared.
- Information required for the manufacturer and country that manufacturers the product. If the medical device consists of components from different suppliers, the manufacturer is the assembly site.
- Require certificate of free sale.
- Stability of IVD studies conducted in the zone.
- Labelling must include manufacturer plus sterilization sites.

Brazil

- Flourishing auditing requirements from the Brazilian government may limit the availability of advanced medical devices and diagnostics in Brazil.

Future Milestones

- Get formal invitation to join GHTF Study Group 1.

- Ensure governments use GHTF Guidance documents.
- Promote training.
- Speed up the translations.

8 **Update on the Recent Steering Committee Meeting**

GHTF/SG1/N055 *Definition of the Terms Manufacturer, Authorised Representative, Distributor and Importer* was submitted to the Steering Committee (SC) for advancement as a Final Document. The SC approved the document as a final document – the document will be uploaded on the GHTF website in the coming weeks.

The GHTF/SG1/N063 *Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices* was approved by SC for advancement as a Proposed document. The document will be posted for public consultation on the GHTF website in the coming weeks. A 6 month comment period is foreseen.

Work plan – Study Group 1 has no new work items.

The comment period for GHTF/SG1/N065 *Registration of Manufacturers and other Parties and Listing of Medical Devices* will end on September 2, 2009.

SG1 published a total of 5 Final Documents in 2005 and 2006. These documents are now subject to revision.

The SC has discussed the possibility of restructuring the GHTF. According to a proposed new model, Ad hoc Working Groups, consisting of a few experts, would replace existing Study Groups and be responsible for developing guidelines on single topics. They would also ensure the required periodic revision of documents. This model would differ from the current structure in which Study Groups have a broad focus and the responsibility to develop a range of documents in their assigned area of expertise. Questions remains as to how this approach would ensure consistency and cohesiveness across documents currently under the responsibility of single Study Groups.

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

SG1/ Essential Principles of Safety and Performance of Medical Devices

A proposal was made to have the IVD Medical Devices Subgroup review this document's IVD content, and make appropriate revisions, prior to advancing the document as a Proposed Document. The IVD Medical Devices Subgroup will determine whether the document should contain a a separate section for IVD medical devices. The guidance will be sent to the IVD subgroup to address this proposal.

The Technical Report ISO-16142 (issued by ISO TC 210) is a derivative of the GHTF Guidance on Essential Principles. Its not entirely consistent with the GHTF Essential

Principles. COCIR representative Peter Linders will participate in the upcoming ISO/TC 210 meeting and will address this issue with TC 210 and possibly the Central Secretariat of ISO. Peter will inform SG1 of the outcome of the ISO discussions at the next meeting of SG1.

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

Toronto meeting discussions were largely focused on revisions of the labelling document. Despite progress, this document was not finalised. It is expected that final revisions will be made at the next SG1 meeting in Brussels. Subsequent to the Brussels meeting, the document will be sent to the IVD Medical Devices Subgroup for its review at its November 2009 meeting.

11 **Study Group 1 Communications Database**

Contact information is out of date for Latin America and the Caribbean region. Observers from South America and the Caribbean will send current contact information to the Secretary.

Action: Attendees

The database will be revised to incorporate the updated information.

Action: Secretary

12 **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**	**Advanced as a Final Document by Steering Committee, May 2009**		**Final Document 2009/Q4**
Registration of Manufacturers and other Parties and Listing of Medical Devices	**SG1/N065**	**Proposed Document, March 2009 Public consultation underway.**	**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, July 2009.**	**1**	**Proposed Document 2009/Q2**

Revision of SG1 Final Documents				
Essential Principles of Safety and Performance of Medical Devices (revised)	**SG1/N069**	**Document revision underway.**	**2**	**Proposed Document 2010/Q2**
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/Q4**
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.**	**2**	**Proposed Document 2010/Q1**

13 **Date and place of next meeting**

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Next meetings –

- Brussels in 13 – 16th October, 2009, in an EU Commission building with support from Industry Associations – to be confirmed. Hotel suggestions, travel from the airport will be forthcoming
- Meeting location early 2010 not yet determined – action ongoing.
- AHWP – proposing meeting with SG1 in Beijing, China

Action: Chair to provide further details at a later date

SUMMARY OF ACTIONS

For the Chair

- To continue interactions with AHWP and Latin American colleagues in support of membership expansion and ongoing collaboration.

- To provide SG1 with more information on the meeting in Brussels in 13 – 16th October, 2009 when such becomes available.

- To continue reviewing the comments on GHTF/SG1/N43:2005 Labelling for Medical Devices during the next SG1 meeting in Brussels.

- To provide SG1 with more information on the next meeting in Jan or Feb 2010 when such becomes available.

For the Chair and Vice-Chair

- Locations/dates for the meetings in 2010.

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 update the SG1 Communications Database.

Nancy Shadeed and Maria Carballo

- To return to the IVD Medical Devices Subgroup for revision, GHTF/SG1/N41:2005 Essential Principles of Safety & Performance of Medical Devices.

Peter Bischoff-Everding and Benny Ons

- To provide SG1 with more information on the meeting in Brussels from 13 – 16th October, 2009 when such becomes available.

Peter Linders:

- To speak with ISO TC 210 on ISO 16142

All attendees

- All members share thoughts on SC proposal to restructure GHTF as an organization whose work would be conducted by focused Ad Hoc Working Groups rather than longstanding, broader focused, Study Groups.

For all attendees, including the observers

- To provide the Secretary with updated information for the Communications Database.