Minutes

GHTF STEERING COMMITTEE
Meeting
Kuala Lumpur, Malaysia
3 March – 5 March 2008

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Welcome

The meeting was chaired by Larry Kessler (US). The Chair welcomed all participants, who were as follows: from the US, Timothy Ulatowski, Gail Costello, David P. Kelly, Michael Gropp, Terrence Sweeney, Janet E. Trunzo (Vice-Chair); from Canada, Roland Rotter, Stephen Dibert; from Japan, Takahisa Murakami, Hiroshi Yaginuma, Shigetaka Miura and Hiroshi Ishikawa from Australia, Rohan Hammett, Rita Maclachlan, Anne Trimmer and Johan Brinch; from Europe, Laurent Selles, John Brennan, Mathias Neumann, Giuseppe Ruocco, Brian R Matthews, Werner Schoenbuehler, Christine Tarrajat, Carl F Wallroth,; from the Liaison bodies Mukundan.Pillay (AHWP) and Remy Baillif (IEC); the Study Group Chairs or their Vice Chairs Ginette Michaud (by phone), Jorge Garcia, Gunter Frey (Vice Chair), Tim Missios (Vice Chair) and Greg LeBlanc (Vice Chair) ; for the Secretariat Jean Olson.

Dr. Pillay said that Malaysia and AHWP were honoured to host the meeting and looked forward to the joint AHWP/GHTF meeting on 4 March 2008.

Also attending the meeting as observers or participants were: Hideki Asai (from Study Group 3), Bjorn Fahlgren (WHO) (by phone), Maurice Freeman (GMDN), Jeffrey Gren (US Department of Commerce/APEC), and Beth Pieterson (Health Canada) (by phone).

Approval of the agenda

The Agenda was approved with the recommendation that an update on Unique Device Identifier (UDI) be added.

Update GHTF Steering Committee Membership List and Contact Details

A listing, printed from the web-site was circulated. Steering Committee members were asked to update the list either directly to the Secretariat now or in the future by e-mail.

Summary Records from the 13th Steering Committee Meeting

The summary records of the last meeting were adopted subject to corrections from Ad Hoc Working Group membership and correction of the translator of GHTF documents in section 5.7.

Steering Committee Initiatives

Training Ad Hoc Working Group

The Chair presented a report on the updated Training Strategy Discussion Paper that had been circulated earlier raised several issues including the relationship between training and GHTF participation; the potential curriculum of GHTF training; and the training materials. Additional issues raised include: who should conduct training; when and where to conduct training; and how to address resource issues.

The updated Training Paper proposed that initially the training be conducted by trainers that had served on GHTF Study Groups or the Steering Committee. It recommended that a committee consisting of GHTF Steering and Study Group members should meet to develop an options paper on trainers.

The updated Training Paper recommended writing letters to candidate training partner organizations and provided a list of criteria encompassing medical device training experience, curriculum development experience, profit status, experience providing training in many geographic areas, experience performing evaluations and providing feedback, and experience providing web-based training.

The updated Training Paper also recommended that the potential training partners have a mechanism to handle registration and payment electronically and be able to invest money collected to help defray the cost of providing current or future training.

The Training Paper was accepted by the Steering Committee.

Translation/Copyright Issues

The Chair noted that the webmasters expected to post links to translated documents on the website once the disclaimer language was provided. Noting the absence of procedures, Mr. Gropp offered to propose changes to the procedural documents to include procedures for translation of documents.

The Chair noted that GHTF had received requests for permission to publish translated documents. The requester wanted to hold the copyright on the translated documents. The Chair further noted that under United States and Canada law, it was lawful for translators to claim a copyright on translated GHTF documents. The Chair asked the Australia, European and Japanese regulators to report back to the Steering Committee on the lawfulness of translators to hold a copyright on translated GHTF documents in their countries.

After discussion it was decided that translators should be asked to translate the GHTF documents in whole, to not modify the documents, to use good quality control, and to use the provided disclaimer.

Mr. Gropp and Mr. Ishikawa volunteered to develop a policy statement on copyright. Ms. Trimmer and the Secretariat volunteered to assist with the statement. It was further suggested that it would be helpful if a lawyer familiar with copyright reviewed the policy as well.

Asian-Pacific Economic Cooperation (APEC) Proposal

Mr. Gren presented a US proposed APEC Proposal for Medical Device Regulatory Harmonization Delegation Visits from Asia and Latin American APEC Economies with Developing Regulatory Regimes to GHTF Founding Member Economies. The US proposed APEC funding for two limited size delegations (15 – 25 officials each) of medical device regulators from APEC economies with developing regulatory regimes to visit APEC economies with developed medical device regulatory regimes (GHTF founding member economies). The GHTF founding member economies proposed to be visited were Australia, the United States, and Canada. Funding was being requested for two separate delegation visits: one from Asia, and the other from Latin America. A similar program was funded last year. Delegation members would participate in regulatory briefings and medical device firm visits to further their understanding of application of harmonized international standards and to witness the benefits of their use. He noted that APEC needed at least a 5 month window to do the program. Mr. Kelly thanked Mr. Gren for the work that he and APEC had done with GHTF.

Ad Hoc Working Groups – Proposal for possible adoption

The GHTF Roles and Responsibilities and the GHTF Operating Procedures had been revised to include procedures for the Ad Hoc Working Groups. Dr. Roland made a motion to approve the revisions. The Motion was accepted by the Chair. No one opposed. The revised documents were accepted.

After a brief discussion it was agreed that a separate procedure to maintain Ad Hoc Working Group papers was not needed. The papers would be maintained as were the other Steering Committee papers.

Global Model Ad Hoc Working Group

Mr. Ulatowski presented an update of the GHTF Global Model Ad Hoc Working Group (AHWG). He noted that the mission had been expanded to include a model for developing regulatory systems. The Global Model AHWG had been meeting to compile relevant background material and discuss courses of

action. The deliverable will be a document that explains the model. The Global Model AHWG intends to provide another document for the Steering Committee in time for the October 2008 meeting in Mexico.

The Chair asked who the Global Model AHWG considered as the audience of the global model. Mr. Ulatowski responded that 3 separate audiences were identified. The audiences included countries with emerging regulatory systems, GHTF itself by identifying gaps in GHTF's documents or system, and persons that were examining the usefulness of the GHTF model and work. Ms. Maclachlan noted that one major challenge was to find a common language to discuss the model. Dr. Garcia suggested that the model was somewhat Study Group 1 centric. Mr. Fahlgren supported the work and suggested that GHTF communicate regularly with WHO on the subject.

Health Technology Assessment International (HTAi) Ad Hoc Working Group

Dr. Rotter updated the Steering Committee on relations with Health Technology International (HTAi). Dr. Rotter noted that he had scheduled a meeting on 27 March 2008 with HTAi. The Steering Committee asked that Dr. Rotter communicate with HTAi regularly.

ISO Council Committee on Conformity Assessment (CASCO) Possible Liaison

Mr. Missios also noted that in discussing a possible relationship with CASCO, that CASCO offered GHTF a D-Liaison relationship. Both Study Group 3 and 4 supportt the Steering Committee approving the D-Liaison relationship. The Steering Committee had yet to see a copy of the proposed D-Liaison relationship. The Steering Committee hoped to receive the document in time to discuss at the upcoming April Telephone Conference.

Action Item: Mr. Missios was asked to forward the D-Liaison relationship to the Steering Committee so that they could be sure what was proposed.

Software Ad Hoc Working Group

Mr. Miura noted that the Study Groups do not include software experts, and asked whether it would be helpful for the Software AHWG to draft language to forward to the Study Groups. The Steering Committee agreed that providing such language would be helpful to the Study Groups. Mr. Muira also agreed that it would be useful to document examples and provide reasoning for suggested modifications to the Study Groups.

New Issues Re ISO 13485 Timing of Revision

After a brief discussion, the Steering Committee stated that it intends to monitor the timing of the revision of ISO 13485, but currently will not make any recommendations regarding the timing of revision.

Cooperation with international bodies

International Electrotechnical Commission (IEC)

Dr. Baliff updated the Steering Committee on IEC. He noted that IEC had established a new affiliate country program that permitted countries to participate in IEC work. Currently 78 countries participate. Participation does not include voting on documents. IEC intends to measure the results of the program after 5 years.

Dr. Baliff noted that the next meeting of TC62 will be in Aukland to finalize the third edition of IEC 60601-1.

Standards Report

Dr. Wallroth updated the Steering Committee on standards issues. The Standards Report discussed the AAMI/Human Factors Engineering Committee and proposed that the GHTF Steering Committee take the following action: develop a long-term vision through 2015 on how to regulate continual improvement at the product level, including situations where devices already in use are being modified, without the requirement that they be considered recalls. This proposal was discussed by the Steering Committee. It was suggested that GHTF first consider how the GHTF documents would be affected, in part because of the difficulty in implementing the suggestion. It was further noted that there was some disagreement within European industry on this subject. After discussion it was decided that the proposed action needed further development prior to GHTF responding. Mr. Ulatowski and a member of Study Group 3 were asked to confer with Mr. Wallroth further and come back to the Steering Committee for the meeting in October for further discussion before the Steering Committee.

The report proposed an additional action: GHTF Steering Committee to instruct Study Group 1 to review and update with high priority the SG1 N041 document on Essential Principles of Safety and Performance for Medical Devices to reflect the amended regulatory requirements (recently published European Directive 2007/47/EC amending the Medical Device Directives 93/42/EEC and 90/385/EEC). After discussion, the Steering Committee asked Study Group 1 to consider the revision to the EC regulatory requirements when they revised the SG1/N41R9:2005 *Essential Principles of Safety & Performance of Medical Devices* document.

The report proposed an additional action: GHTF Steering Committee to request the GHTF member countries to evaluate the situation in their jurisdiction and to report back to the Steering Committee for possible harmonization of the transition periods. The Steering Committee discussed the recommendation on transition periods for standards and whether this was a regulator prerogative. The Steering Committee questioned whether this was an appropriate issue for GHTF. And it questioned whether the Steering Committee had sufficient time to get into the level of detail required to properly assess this proposed action. It was decided to leave this issue to the Standard Development Organizations.

There followed a brief discussion on how to prioritize those standards issues that need to be on the GHTF Steering Committee agenda to alert the Steering Committee to pertinent issues in the standards community.

Action Item: By 31 March 2008, members were asked to forward to the Chair comments on the whether there should be a change in scope and direction of the Standards Report. The Chair will forward a proposal for the upcoming telephone Conference.

Action Item: Australia, EU, Japan and US to forward the Delta List information to Dr. Wallroth.

Upcoming meetings

- **5-7 October 2008 Steering Committee Meeting in Mexico**
- **GHTF/APEC Training, 8-10 October 2008 in Mexico**
- **10-15 May 2009 GHTF Conference in Toronto, Ontario, Canada**
- **1-4 November 2009 Steering Committee Meeting in Vancouver, British Columbia, Canada**

Mr. Rotter noted that the exact location of the meeting in Mexico was not established quite yet.

Study Group's work - Progress reports and documents

Study Group 1

Dr. Michaud updated the Steering Committee on the work of Study Group 1. Dr. Michaud noted that Study Group 1's membership had expanded to include representatives from Latin America and the Caribbean. Dr. Michaud reviewed Study Group 1's Work Plan and discussed the documents it was advancing as final documents.

Study Group 1 presented SG1/N44 *Role of Standards* for approval as a final document. Dr. Michaud noted the revision of the language dealing with transition period. A discussion ensued. Dr. Michaud was requested to slightly modify the transition period language to clarify the transition period language.

Action Item: SG1/N44 *Role of Standards* was approved for posting as a final document after the transition language was modified.

Dr. Michaud presented SG1/N011*Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED),* SG1/N046*Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices* and SG1/N045*Principles of In Vitro Diagnostic (IVD) Medical Devices Classification* for advancement as final documents at an upcoming Steering Committee Telephone Conference in April. Dr. Michaud said that Study Group 1 has clarified the *STED* document and provided a greater depth of details. She noted that the delegates from the AHWP provided significant assistance in this process, as well as in harmonizing STED with the Common Dossier Template. She further explained that a number of comments had been resolved to finalize the two IVD documents.

Action Item: Members with significant comments on the *STED* document are asked to forward them to the Secretariat by 10 April 2008.

Dr. Michaud updated the Steering Committee on the work done on the Definition of Manufacturer document at the meeting in Bonn, Germany. She noted that the document would be distributed to all of the Study Group members prior to distribution to the public. The Study Groups hope to have the document ready for public comments by the third quarter of 2008.

Study Groups 1, 3 and 4 are working on a Registration and Listing document. It is being developed in face-to-face meetings. Study Groups 2 and 5 have been commenting on the drafted language electronically after drafts of language are forwarded oto them for consideration.

The Chair asked Dr. Michaud and the other Study Group Chairs whether the Study Groups had opinions on how best to collaborate with AHWP's Technical Committees. Dr. Michaud noted that Study Group 1 had worked with AHWP by having AHWP observe meetings, AHWP had been asked to staff Study Group 1 meetings with two members from AHWP, and Study Group 1 had joint meetings with AHWP. Mr. Frey and Mr. Missios agreed that a varied approach worked best for Study Group 3 and 4 respectively. Depending on the project, one or other of the approaches might work best. All the Chairs supported outreach in working with AHWP.

The Chair took the opportunity to ask all of the Study Group Chairs to take into account the Steering Committee meetings in the timing of Study Group meetings. It would be helpful if documents ready for proposed or final consideration could be ready in sufficient time for an upcoming Steering Committee meeting.

Study Group 2

Dr. Garcia updated the Steering Committee on the work of Study Group 2. He noted that Study Group 2 had finished work on the NCAR documents, and had

some minor work to finish on SG2/N38R15 *Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program*. SG2(PD)N87/R7 Post Market Surveillance: An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives, and National Competent Authorities needs minor adjustments to the documents. The Germany, Australia, United Kingdom pilot has extended the timeline to the third quarter of 2009.

The Steering Committee discussed Study Group 2's New Work Item: Definition and Classification of Recalls and Associated Product Safety Corrective Actions. While there was general support for the work item the Steering Committee asked that Study Group 2 work on the scope of the work item. The work item was approved with a direction to provide an interim report on the work to the Steering Committee.

Action Item: Dr. Garcia was asked to bring a revised scope of work for the April 2008 Telephone Conference. Dr. Garcia was asked to include a list of other organizations that may have a stake in the issue.

Study Group 3

Mr. Frey updated the Steering Committee on the work of Study Group 3. Mr. Frey noted that a new technical expert with significant US industry experience with CAPA was assisting Study Group 3 on its work on N18 *Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activit*es

Action Item: Members of the Study Groups and the Steering Committee were asked to have comments to Study Group 3 by the end of April on SG3(WD)N17 - *Guidance on the control of products and services obtained from suppliers*. The Chair acknowledged that some members may need extra time to submit their comments but asked members to please not delay their comments.

Study Group 4

Mr. Missios updated the Steering Committee on the work of Study Group 4. He noted that the comment period for SG4(PD)/N28R3 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements* would close on 14 May 2008. Mr. Missios noted that Study Group 4 continues its work on SG4 (WD)N83 - *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 1 Multi-site Audits and Audits of Suppliers* and SG4 (WD)N84 - *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 2 Auditing of Supplier Control*.

Action Item: Mr. Missios was asked to thank Mr. Zobrist for his work on and as Chair for Study Group 4.

Action Item: The Chair was asked to write Mr. Zobrist and express the appreciation of the Steering Committee for his work on Study Group 4, and his work as Chair.

Study Group 5

Mr. LeBlanc updated the Steering Committee on the work of Study Group 5. He noted that *Clinical Investigations* Working Draft document had been forwarded to the Steering Committee for review. The Steering Committee approved posting the document as a proposed document.

Mr. LeBlanc also discussed New Work Item: Adverse Incident Reporting during clinical investigations for medical devices. A discussion followed concerning whether this Work Item more properly belonged under the Study Group 2 or Study Group 5. It was decided that Study Group 2 should take on the New Work Item. Study Group 2 should collaborate with Study Group 5 on the New Work Item.

AOB

Action Item: The Secretariat is directed to ensure that all members are identified by a member organization on the GHTF Website.

During the meeting, the Chair read a letter to the Steering Committee. The letter was addressed to Michael Cheng of Canada and apologized for a previous letter that had questioned Mr. Cheng's work and intentions with respect to GHTF.

Action Item: The Chair and the Vice Chair of GHTF Steering Committee as well as the upcoming Chair and the upcoming Vice Chair were asked to meet with the Chair and the Vice Chair of AHWP to discuss strengthening the conversation between GHTF and AHWP.

Dr. Rotter expressed deep appreciation on the part of the Steering Committee for the Chair's work for GHTF. Ms. Maclachlan and Mr. Ulatowski also thanked the Vice Chair, on behalf of the Steering Committee, for her work for GHTF. The Steering Committee further thanked the Secretariat for her work on behalf of the Steering Committee.

Mr. Dierk Bellwinkel's recent death was noted and the Steering Committee took a moment to remember him and his service to GHTF, particularly his tenure as Secretary of Study Group 4.

CLOSED SESSION

Global Medical Device Nomenclature (GMDN) Ad Hoc Working Group

Dr. Hammett updated the Steering Committee on the work of the Ad Hoc Working Group. The Chair thanked Mr. Freeman for his presentation and his participation. Dr. Hammett and Mr. Freeman agreed to meet in London in March.

Action Item: GHTF and AHWP agreed to forward a possible future business model to Mr. Freeman.

Combination Products Ad Hoc Working Group

Ms. Maclachlan updated the Steering Committee on the work done by the Combination Products AHWG.

Action Item: Mr. Ulatowski will forward a copy of the FDA letter on combination products to entire Steering Committee.

Maintenance Mode Ad Hoc Working Group

Mr. Neumann updated the Steering Committee on the work of the Maintenance Mode AHWG.

Action Item: Steering Committee asked to forward comments on option preferences to Mr. Neumann.

Process Improvements Ad Hoc Working Group

Mr. Kelly updated the Steering Committee on the work of the Process Improvements AHWG.

Action Item: Members were requested to forward comments on Process Improvement Report by end of March to Mr. Kelly, Ms. Trimmer and Mr. Ishikawa by 31 March 2008.

International Accreditation Forum (IAF) Ad Hoc Working Group

Dr. Rotter updated the Steering Committee on the work of the IAF AHWG.

Action Item: Dr. Rotter to prepare a proposal regarding a possible confidence building pilot.

Retrospective Report

Ms. Pieterson presented the Retrospective Report to the Steering Committee. The Chair thanked Ms. Pieterson and her team for the report.

Action Item: Members are asked to submit comments on Retrospective Report to Secretariat for compilation and forwarding to Beth Pieterson and her team by end of April.

Action Item: AHWG asked to submit comments on Retrospective Report to Dr. Rotter by 15 April 2008.

***Clinica* Article discussion**

The Steering Committee noted that an opinion piece regarding GHTF had been written in *Clinica* and decided after a brief discussion that a response to the piece was unneeded.

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