

Record of Discussions
19th GHTF STEERING COMMITTEE MEETING
2-4 NOVEMBER 2010
Sydney

Participants: AUSTRALIA	Organization
Larry Kelly - Chair	TGA
Anne Trimmer - Vice Chair	MTAA
Rohan Hammett	TGA
Johan Brinch	Cochlear Limited
Linda Martin - Secretariat	TGA
Frank Marando - Secretariat	TGA
Participants: CANADA	Organization
Roland Rotter	Health Canada
Stephen Dibert	MEDEC
Participants: UNITED STATES	Organization
Lillian Gill	FDA
Gail Costello	FDA
Michelle Limoli	FDA
Janet Trunzo	AdvaMed
Terrence Sweeney	AdvaMed (Philips Medical System)
Michael Gropp	AdvaMed (Medtronic, Inc)
Participants: JAPAN	Organization
Toshiyoshi Tominaga	PMDA
Kentaro Azuma	MHLW
Hiroshi Ishikawa	Toshiba Medical Systems
Shigetaka Miura	JFMDA (Sakura Seiki)
Participants: EUROPE	Organization
Laurent Sellès	European Commission
Matthias Neumann	Federal Ministry of Health - Germany
Giuseppe Ruocco	Ministry of Health - Italy
Joanna Kilkowska	Medical Devices Department - Poland
Benny Ons	EDMA (BD Bioscience)
Nicole Denjoy	COCIR
Francois Simondet	Air Liquide Sante' International, EUROM VI (Medical Technology)
Participants: LIAISON BODIES AND OTHERS	Organization
Lindsay Tao - Observer	AHWP
REGRETS	Organization
Jean Yves Carentz	Stryker

1. Welcome

L. Kelly and A. Trimmer welcomed all members to the Steering Committee (SC) meeting.

L. Kelly welcomed Francois Simondet to his first face to face GHTF Steering Committee meeting.

The Chair advised that Jean Yves Carentz sent his apologies for the meeting.

2. Approval of the Agenda

L. Kelly sought advice from SC members on any items to be added under Other Business. The following items were proposed:

- Medical software (N. Denjoy)
- GHTF Conference (A. Trimmer)

The amended Agenda was approved.

3. Update Steering Committee Membership List and Contact Details

SC members were asked to update the contact list and return the document with any changes to the Secretariat.

Action Item:

- *GHTF Secretariat will post the revised and updated list to the website.*

4. Approval of Record of Proceedings from August 2010 Steering Committee Teleconference

The Record of the August 2010 teleconference was accepted, with some minor amendments.

Action Item:

- *GHTF Secretariat will post the final Record of Proceedings on the secure website.*

5. GMDN Update

J. Trunzo provided an update on GMDN. She advised that the Annual General Meeting of the GMDN Agency was held at the end of September 2010. J. Trunzo advised that the Board of Trustees has been expanded to include two representatives from AHWP.

Discussion at the meeting centred on financial structures and liaison with other Agencies. J. Trunzo advised that further teleconference calls were scheduled to progress these discussions and to welcome the new representatives from AHWP. The next teleconference is scheduled for December 2010.

J. Trunzo also indicated that the most important current issue for the GMDN Agency with respect to GHTF is the receipt of a supporting statement from GHTF stating that GMDN is the preferred global nomenclature system for medical devices. (Discussed further at Agenda Item 12).

M. Neumann sought advice on the timeframe for the improvement of internal processes in the GMDN Agency. J. Trunzo advised that significant progress has been made on the roles of the Trustees, including issues around transparency, pricing models, assessing alternate funding mechanisms, budget, finance, and structure. Work was still progressing on the procedural documents around these issues. She also noted that the goal of the Trustees is to fully implement the GHTF recommended governance structure.

J. Trunzo advised that the Policy Advisory Group (PAG) has provided a list of recommendations to the Board of Trustees relating to the experience of users in accessing GMDN. Many of these recommendations will also require procedural changes.

L. Kelly brought to the attention of SC members, a PAG paper on the “Use of GMDN in a Regulatory System”. The paper had been circulated prior to the meeting as PAG had asked that SC members be made aware of the document and sought advice on whether this was in line with the SC thinking. PAG also sought advice on whether the document could be integrated as a GHTF document.

Members, particularly some of the industry members, thought it was a very useful document even in its draft form and recognising it still required development. It was agreed that in future revisions of GHTF guidance documents, GHTF would look to include references to the final PAG document. There was also a suggestion that it may be helpful to include some visual representations as a way to simplify the presentation of the material.

Action Item:

- *L. Kelly to write to Susanne Hoeke advising that the SC, although not proposing to develop the draft into a GHTF document at this time, thought it was a very useful document and would, in future revisions, consider integrating references in GHTF documents to the PAG document.*

6. Update of Main Developments in Founding Members' Regulatory Systems

Canada

R. Rotter provided an update from the Canadian regulator perspective. He informed the SC of new senior management appointments, provided information on current regulatory activities, HPFB and medical devices program activities, including information on Canada's move towards the implementation of a new cost recovery model.

Europe

L. Sellès provided an update from the European regulator perspective. He informed the SC that the European Commission has a new Commissioner, John Dalli, who has provided a critical guidance for proposed achievements in the next four years. L. Sellès also provided advice on recent structural changes. It has been agreed with the European Commissioner that a recast proposal will be put forward to the College of Commissioners and the Parliament and Council in the first quarter of 2012. The proposal will cover two directives - one on medical devices, and the other on *in vitro* diagnostic medical devices.

Japan

K. Azuma provided an update from the Japanese regulator perspective. He informed the SC about new growth strategies and the healthcare industrial policy, and provided an update on medical device regulation. He also provided the SC with advice on the latest structure of the Pharmaceutical and Medical Devices Agency, and the Agency's intention to significantly increase the number of resources in the medical device area over the coming years. K. Azuma also provided information on the introduction of a prior assessment system for brand-new medical devices, the guidance for emerging technologies, third party certification standards update, and the Essential Principles checklist. K. Azuma also provided SC members with a list of registered certification bodies in Japan.

United States

L. Gill provided an update from the US regulator perspective. She informed the SC of a number of staff changes in the FDA, as well as changes in responsibilities. She advised that the Centre for Biologics Evaluation and Research was expanding with the construction of two new laboratories expected to be completed in two years. L. Gill noted that the FDA was looking to bring more transparency in its decisions by increasing website publication. She also outlined new guidance that had recently been issued, including IVDs and safety and effectiveness information, as well as a list of proposed guidances that are under consideration.

Australia

L. Kelly provided an update from the Australian regulator perspective. He informed the SC of the recent TGA restructure. He also updated the SC on current TGA reforms including business process reviews, decision making processes, corporate governance changes, and increasing transparency of processes and decisions. He advised that IVD legislation was introduced on 1 July 2010 with a four year transition period, provided details on the TGA and Health Canada MoU on quality system certification exchanges, and went through some of the recommendations from the Australian Government's recent Health Technology Assessment Review, including the

subsequent Medical Devices Regulatory Reforms Discussion Paper which has been released for public comment.

7. Presentation by Dr Charles Jaffe, CEO, Health Level 7 International (HL7)

Dr Charles Jaffe, CEO, Health Level 7 International (HL7) provided the SC with a presentation outlining the work of HL7 and its achievements. Dr Jaffe shared his views on the need for a seamless interchange of data and also on the probable obstacles to this occurring. He was keen for HL7 and GHTF to enter into a formal agreement with deliverable outcomes, that would also provide for a methodology and governance for collaboration.

SC members indicated their interest in participating in one of the current projects being undertaken by HL7, the creation of a Regulatory Product Submission for medical devices. Dr Jaffe indicated that GHTF involvement should be provided via the public stakeholder group process.

Subsequent to Dr Jaffe's presentation, the SC decided that, given GHTF's current key areas of interest relate to technical areas of expertise, the most effective input would be provided via its Study Groups. The SC endorsed the continued liaison between HL7 and SG1 at a technical level, on the proviso that SG1 seek the appropriate range of inputs in liaising with HL7, in particular, in relation to electronic submissions for notified conformity assessment bodies.

Action Items:

- *L. Kelly to write to Dr Jaffe thanking him for his presentation. The letter will inform that GHTF will continue to liaise with HL7 through SG1, and that a formal arrangement via an MoU will not be pursued at this time.*
- *L. Kelly to write to the SG1 Chair advising that the SC endorses the continued liaison with HL7, and requesting that they extend their consideration to take in other regulatory approaches, such as European notified bodies.*

8. Study Groups Work – Progress Reports and Documents

SC members discussed the current position in relation to the ongoing functioning of Study Groups when their respective workplans are complete. Members reaffirmed their previous viewpoint that Study Groups continue to work on tasks assigned to them by the SC and that the SC may determine if new work is to be assigned to a Study Group. However, once the work of a Study Group is completed, the Study Group would disband. Individuals from the Study Group would be asked if they would agree to be on an expert list which would be used to revise documents, assist in responding to ongoing enquiries about the Study Group's work, or to work on new issues as part of an Ad Hoc Working Group.

Action Item:

- *L. Kelly to reaffirm to Study Group Chairs the previous advice regarding the completion of their workplans.*

8.1 Study Group 1

N. Shadeed provided a written update report on the activities of SG1. The report was noted by the SC. It was also noted that S. Tang will take over the chairperson duties of the IVD subgroup after their December meeting.

Action Item:

- *L. Kelly to write to N. Shadeed thanking her for the update and commending the Group for their outreach work to AHWP and the Latin American Harmonization Working Party.*

8.2 Study Group 2

I. Demade provided a written update report on the activities of SG2. The report was noted by the SC, particularly their work to take the GHTF message more globally, including liaison with AHWP. The SG2 Chair had provided a draft working document SG2/N111R5 – Definition and Classification of Field Safety Corrective Actions – for the information of the SC.

Action Items:

- *L. Kelly to write to I. Demade (SG2) to clarify the relationship between document GHTF/SG2/N111R5:2010 and GHTF/SG2/N57R8:2006.*
- *L. Kelly to remind I. Demade (SG2) that the SC had asked (at the Singapore meeting) for a new work item to be submitted for SC consideration on a proposal to review N57R8:2006*

8.3 Study Group 3

E. Cobbold provided a written update report on the activities of SG3. The report was noted by the SC.

8.4 Study Group 4

J. Welch provided a written update report on the activities of SG4, noting that the workplan of Study Group 4 is complete. The report was noted by the SC.

Action Item:

- *L. Kelly to write to SG4 to thank them for their services, advise them that SG4 is disbanded, and ask them to nominate a small number of experts in the event that any issues of relevance from SG4's work should arise.*

8.5 Study Group 5

S. Ludgate provided a written update report on the activities of SG5. The report was noted by the SC.

9. Ad Hoc Working Group Items

9.1 Global Model Ad Hoc Working Group Update

J. Brinch provided the SC with an update on the work of the Global Model Ad Hoc Working Group. He advised that the working group was aiming to submit the revised document to SC members for initial comment in November or December 2010, with the possibility that the SC could consider the work as a final document at the teleconference in March 2011.

9.2 Unique Device Identifiers Ad Hoc Working Group Update

L. Sellès provided the SC with an update on the work of the Unique Device Identifiers (UDI) Ad Hoc Working Group. Details on the discussion about the covering letter and the Draft Guidance Proposal on UDI for Medical Devices is provided under Item 15.

Action Item:

- *B. Ons to advise Study Group 1 to consider references to the UDI document when undertaking their review of the labelling document (SG1-N43:2005).*

9.3 Regulatory Change Management Ad Hoc Working Group Update

L. Kelly provided the SC with an update from Gary Burgess (Chair of the Group) on the work of the Regulatory Change Management Ad Hoc Working Group. L. Kelly advised that the Working Group was continuing to refine the guidance document, ready for external release in early 2011.

10. Standards Rapporteur

10.1 Rapporteur Update

N. Denjoy provided the SC with a Rapporteur update. She highlighted some concerns in relation to the ISO Technical Committee 210. The SC agreed to liaise directly with ISO to draw attention to the importance of maintaining compatibility of ISO 13485 with the regulatory requirements for medical devices quality management systems and the need for flexibility in the implementation of the common ISO Management System Standards structure in the medical devices sector.

Action Items:

- *N. Denjoy to write to Study Group Chairs to seek updates to ensure the entire list of relevant TCs is covered by the Standards Rapporteur.*

- *L. Kelly to write to ISO and IEC managements to ask that GHTF is listed automatically as a liaison body in relation to the relevant TCs.*
- *L. Kelly to consult with the SG3 Chair to ensure that SG3 agree with the wording in the documents distributed under Item 10.1.*
- *SC to be given two weeks to consider the papers distributed by N. Denjoy at the meeting on Item 10.1. SC members to provide comments to N. Denjoy. Following receipt of comments N. Denjoy will advise L. Kelly of wording for raising concerns with ISO prior to their February 2011 meeting.*

10.2 Proposal Regarding the Mandate of the Standards Rapporteur

N. Denjoy presented a paper on the proposal regarding the mandate of the Standards Rapporteur. The SC agreed to the proposed Standards Rapporteur mandate as tabled.

10.3 Proposal to Establish a Standards Ad Hoc Working Group

N. Denjoy presented a paper on a proposal to establish a Standards Ad Hoc Working Group.

The SC did not support the establishment of a Standards Ad Hoc Working Group at this stage. It was agreed that some further discussion between the regulators was required out of session to consider whether a Standards Ad Hoc Working Group is required.

Action Item:

- *M. Neumann will engage in out of session discussions with regulators about whether a Standards Ad Hoc Working Group should be established, with the possibility of considering a reformed proposal at a future SC meeting.*

11. GHTF Operating Procedures Document

A. Trimmer provided an overview for SC members on the changes made to the GHTF Operating Procedures Document.

The SC agreed to delete the words “.... including disbanding the relevant group and re-assigning the work” from paragraph 3.1 General Principles.

Subject to this amendment, the SC agreed to the GHTF Operating Procedures Document being progressed as a Final Document.

Action Items:

- *Secretariat to publish final document on GHTF website.*
- *A. Trimmer to update Format and Style Guide with corresponding changes.*

12. Draft Website Statement Regarding Use of GMDN

It had previously been agreed by the SC at the August teleconference that the Chair would draft a statement for the GHTF website signalling GHTF's support for the use of GMDN. The draft document was circulated to SC members with the meeting papers, and L. Kelly invited comments.

The SC agreed to some amendments to the draft statement so that it endorses GMDN as the preferred nomenclature system for regulatory purposes for medical devices. It was also amended to highlight that GHTF is working actively on ways of making this nomenclature more accessible globally.

Action Item:

- *GHTF Chair to circulate the website statement to SC members for confirmation, prior to the statement being placed on the GHTF website.*

13. SG1/N063:2010 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of *In Vitro* Diagnostic Medical Devices

M. Neumann advised that the European regulators had a number of substantial concerns with the paper 'SG1/N063:2010 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of *In Vitro* Diagnostic Medical Devices'.

SC members expressed concern that a document could reach the stage of consideration by the SC, without significant comments being addressed. B. Ons advised that the comments from the European regulators had been considered by SG1, but not incorporated.

B. Ons proposed that the comments from the European regulators be re-submitted with further details, and that the IVD sub-group could have further discussion out of session around these concerns, and if any comments are not adopted, the IVD sub-group will provide an explanation as to why they have not been adopted. The SC will see the outcome of this consideration at the March teleconference.

Action Item:

- *European delegation of the SC to write to SG1, re-submitting the previous comments with further details.*

14. SG3/N18 – Quality Management System (QMS) – Medical Devices – Guidance on Corrective Action and Preventative Action and Related QMS Processes

The SC agreed that the paper ‘SG3/N18 – Quality Management System (QMS) – Medical Devices – Guidance on Corrective Action and Preventative Action and Related QMS Processes’ can be progressed as a Final Document.

Action Items:

- *L. Kelly to write to SG3 Chair, thanking SG3 for their work on this item.*
- *Secretariat to post SG3/N18 on the website as a Final Document.*

15. Draft Guidance – Proposal on UDI for Medical Devices

L. Sellès presented the covering letter and Draft Guidance – Proposal on UDI for Medical Devices. The SC agreed that the information provided in the covering letter should be included as a preamble in the Draft Guidance – Proposal document, so that all the information is contained in a single document.

L. Kelly sought advice from the SC whether the document could be posted on the GHTF website, despite the document not being circulated for the full eight weeks for consultation.

K. Azuma advised that Japanese regulators required more time to consult and consider the document prior to it being posted on the GHTF website for comment. Later in the meeting K. Azuma provided advice that Japanese regulators had no further comments on the document.

Action Item:

- *GHTF Secretariat to arrange for the Draft Guidance – Proposal on UDI for Medical Devices, as amended to include the information in the covering letter as a preamble, to be posted on the GHTF website with a six month comment period.*

16. Update Regarding ISO 13485

M. Neumann provided SC members with an update on ISO 13485. M. Neumann had liaised with SG Chairs to seek their input and views on an early progression to an update of ISO 13485. Only one technical comment had been received.

SC members agreed that consultation with ISO in relation to ISO 13485, should be through SG3, and that this information should be provided to all SG Chairs.

Action Items:

- *L. Kelly will write to SG Chairs advising that GHTF consultation with ISO in relation to ISO 13485 will be through SG3 and that the SC is proposing to write to ISO (Chair of TC210) to express concerns using the document prepared by M. Neumann as a basis (Titled 'Improvement of ISO13485').*
- *M. Neumann to draft a letter to ISO providing general comments and pointing out where GHTF has concerns/considers there are deficiencies, and indicating that GHTF contact will be via SG3.*
- *GHTF Secretariat to circulate proposed ISO letter to SC members for comment.*
- *Pending agreement from SC members, letter will be sent from L. Kelly to Chair of TC210.*

17. Training Strategy

17.1 Managing Requests for Training

The SC agreed that the Chair and/or Secretariat would continue to respond to straight forward general requests that were received. At the discretion of the Chair, issues that require SC consideration will be brought to the attention of members.

17.2 Draft Website Statement Regarding GHTF Training

The SC discussed the draft website statement that had been circulated with the meeting papers. Japanese regulators raised concerns about placing a statement about training on the GHTF website. The SC agreed that any website statement regarding GHTF training would not be posted on the website until there are clear procedures in place on how to handle training requests, which was also the subject of discussion.

The SC had an extensive discussion on the future GHTF training strategy and how this will be implemented. A. Trimmer agreed to bring together into one document a summary of previously agreed outcomes to create a training strategy. This will then be circulated to SC members. Following this work, L. Gill volunteered to draft a document setting out how the GHTF training strategy will be implemented. This work may or may not require a sub-group of SC members and will be reconsidered at a future time.

Once the GHTF has an agreed strategy and implementation plan, further consideration will be given to a training statement on the website.

Steering Committee members and Study Group Chairs were reminded of the need to inform the chair before delivering training on GHTF material.

Action Items:

- *A. Trimmer to review previous GHTF documents and decisions in relation to GHTF training, with the aim of summarising previously agreed outcomes into a GHTF training strategy.*
- *Secretariat to remind SC and Study Group Chairs of the need to inform the Chair before delivering GHTF training.*

17.3 Outcomes of Contact with RAPS, AHWP, MTLI

L. Kelly advised SC members that as previously agreed, he has made contact with RAPS, AHWP, and MTLI about exploring some training options.

The SC agreed that L. Kelly continue to explore these options while the training strategy is being refined.

Action Item:

- *L. Kelly to continue communication with RAPS, AHWP, and MLI – in the short term advising them that once the internal training strategy matures the SC will again contact them.*

17.4 Panama Training Request

L. Kelly sought advice from SC members about whether any region would be interested in assisting with a training request from Dr Itzel Thomas in Panama. R. Rotter advised that once each year Health Canada and the USFDA each conduct training programs on regulatory programs and procedures.

Action Item:

- *L. Kelly to write to Dr Thomas indicating that it is pleasing to see Panama interested in the GHTF model, and suggesting that they contact Health Canada regarding their annual regulatory training program, and also suggesting it may be feasible to conduct regional training, possibly through PAHO, if there is sufficient interest from the region.*

17.5 SG2/N120R6:2010 – Training for Post Market Surveillance, including the National Competent Authority Report Exchange Programme

The SC noted the draft paper prepared by SG2 regarding training for post-market surveillance, including the National Competent Authority Report Exchange Programme (NCAR). The SC noted some inconsistencies between the title of the paper on the cover page, and the title of the paper on page 4. It also wasn't clear to the SC whether this was an internal working document or a public document. The current format has all the appearances of a public document.

The SC considered that in general the document was very useful and could be used as a model for other SGs.

The SC also considered it important to have a central repository for all GHTF training material. The SC agreed that this material should be sought from SG Chairs.

Action Items:

- *L. Kelly to write to SG2 Chair commending SG2 on their work, noting that the document is useful for their internal working procedures. The letter will also provide feedback on some minor inconsistencies in the titling of the document, and ask SG2 to clarify whether this is an internal document and should have more of a 'look and feel' of an internal document. L. Kelly to remind SG2 there is a formal process for seeking SC endorsement of a document.*
- *L. Kelly to circulate the document to other SGs as a guide or model on how to conduct training in general.*
- *Secretariat to write to each SG Chair seeking copies of their training material. The information will then be held in a central repository within the GHTF Secretariat.*
- *SC members are to send any additional comments on the document directly to the SG2 Chair.*

17.6 Taiwan FDA application for NCAR membership

L. Kelly advised that he had received a recommendation from the Chair of SG 2 that Taiwan Food and Drug Administration become a full participating member of the National Competent Authority Report Exchange Programme (NCAR). A request for consideration will be distributed out of session to SC members.

Action Item:

- *L. Kelly to seek out of session comment from members on the recommendation for Taiwan Food and Drug Administration to become a full participating member of NCAR.*

18. Update on AHWP

18.1 Feedback from AHWP TC Meeting in Taipei; and

18.2 Update on AHWP Activities

L. Tao delivered a presentation which provided SC members with feedback from the AHWP TC meeting in Taipei, and provided an update on AHWP activities. In particular she noted that there were now AHWP representatives on each of the GHTF Study Groups; that there would now be a permanent AHWP secretariat; and that the Chair of AHWP Working Group 6 had commenced liaison with the GHTF Chair in relation to the development on joint training materials. L. Tao also indicated that the invitation to AHWP to become a regional member of GHTF and the possible convening of a joint AHWP/GHTF conference would be discussed at the AHWP meeting being held later in November.

L. Kelly provided the SC with advice on communications with AHWP regarding proposed joint regulatory training.

The SC discussed the proposed joint GHTF and AHWP annual conference in 2011. L. Kelly advised that GHTF had put the proposal to AHWP, and they will consider it at their next meeting.

19. GHTF Strategic Directions Session – Update Following Discussions at May GHTF Steering Committee Meeting – Closed session

Members were reminded that the outcomes from the May SC meeting relating to future directions for GHTF were forwarded to Heads of Agencies for consideration.

Dr Hammett provided feedback from the Heads of Agencies meeting that GHTF should continue to develop a position. He also advised that a meeting of GHTF regulators would likely meet early in 2011 to consider medical device regulation more generally – and that this meeting may assist GHTF deliberations.

Following a general discussion about possible future strategic directions for GHTF it was agreed to form a small working party to progress issues raised with the aim of preparing a paper for consideration by all SC members. Possible options for progressing the establishment of a permanent secretariat were discussed.

Action Items:

- *A sub-group of SC members to provide a detailed analysis on the future strategic direction and structure of GHTF, for consideration by all SC members. The sub-group will comprise of T. Sweeney (Chair), L. Kelly, L. Sellès, K. Azuma, R. Rotter, M. Gropp, N. Denjoy, H. Ishikawa.*
- *T. Sweeney to draft initial draft document for sub-group members to consider.*

20. Other Business

20.1 Briefing on the Relationship Between ICH and Standards Development Organizations (SDOs)

T. Tominaga delivered a presentation informing SC members of the relationship between ICH and SDOs. As a result of the discussion that followed and concerns about the difficulty in gaining GHTF involvement in some ISO committees, it was agreed that the GHTF Chair should write to the Secretary of ISO in relation to the MoU with GHTF and to clarify the nature of the relationship.

Action Item:

- *Chair to write to ISO in relation to the MoU to clarify the nature of the relationship between ISO and GHTF.*

20.2 Distribution and Use of the GHTF Glossary

B. Ons provided the SC with background information on the GHTF Glossary, and sought advice on where the document should be located. The SC considered that the GHTF Glossary should be a stand-alone document, and that a link to the document should be provided on each of the SG web pages. The SC also agreed the GHTF Glossary should be converted from a Proposed Document to a Final Document.

Action Item:

- *GHTF Secretariat to submit a request to US FDA to provide links to a stand-alone GHTF Glossary on each of the SG web pages.*

20.3 GHTF Website – Interested Parties Register

B. Ons made a request for a new feature to be added to the GHTF website to enable interested parties to register themselves so that they can be notified when a new document is placed on the website.

Action Item:

- *L. Gill to check with IT experts in the FDA in relation to the capacity to provide a facility to notify interested parties of new documents and website updates.*

20.4 Report on the WHO Bangkok Meeting

L. Kelly, A. Trimmer and M. Gropp provided feedback to the SC on the WHO First Global Forum on Medical Devices, held in Bangkok. It was noted that much of the interest is in economies that cannot afford to implement a full GHTF regulatory model and that organisations such as WHO are progressing initiatives to make low-cost technologies available to all.

20.5 Single AHWP / ASEAN Observer at SC Meetings

L. Kelly advised that he was approached with a proposal to have an ASEAN observer at GHTF SC meetings. L. Kelly will respond to the request following comments being received from Japan within four weeks.

Action Items:

- *Japan to provide their comments to the GHTF Chair within four weeks, on the proposal to have an ASEAN observer at GHTF SC meetings.*
- *L. Kelly to respond to the ASEAN proposal following receipt of the comments from Japan.*

20.6 Medical Software

N. Denjoy discussed the difficulties in qualifying and classifying medical software. N. Denjoy proposed that the SC request SG1 to conduct some work on finding a harmonized way to deal with medical software. The SC considered that further discussion was required between regulators to attempt to find some common ground between jurisdictions, prior to requesting SG1 to undertake any work in this area.

20.7 PAHO Observer at SC Meetings

M. Limoli reminded the SC that it had previously agreed to PAHO participating in GHTF as provided for under the procedural rules. M. Limoli advised that she had extended an invitation to PAHO for the November SC meeting as an observer, but they were unable to attend. The SC agreed to extend an invitation to PAHO for the May SC meeting in Brisbane.

Action Item:

- *M. Limoli to extend an invitation to PAHO as an observer for the May SC meeting in Brisbane.*

20.8 R. Rotter – Final Meeting

R. Rotter advised that this would be his last GHTF meeting as he will be transitioning his GHTF responsibilities to another representative from Health Canada. He thanked past and present SC members, SG members, and Ad Hoc Working Group members. L. Kelly, on behalf of the SC, thanked R. Rotter for his excellent contribution to GHTF since 2002 including his period as SC Chair.

Reminders

11 March 2011: GHTF SC Teleconference Meeting (Australian time)

11-13 May 2011: GHTF SC face to face meeting – Brisbane, Australia