Record of Discussions
18th GHTF STEERING COMMITTEE MEETING
10-12 MAY 2010
Singapore

Participants: AUSTRALIA	Organization
Larry Kelly - Chair	TGA
Anne Trimmer – Vice Chair	MTAA
Johan Brinch	Cochlear Limited
Linda Martin - Secretariat	TGA
Shawn Hazel - Secretariat	TGA
Participants: CANADA	**Organization**
Stephen Dibert	MEDEC
Participants: UNITED STATES	**Organization**
Lillian Gill	FDA
Gail Costello	FDA
Michelle Limoli	FDA
Janet Trunzo	AdvaMed
Michael Gropp	Medtronic
Terrence Sweeney	Philips Medical System
Participants: JAPAN	**Organization**
Toshiyoshi Tominaga	PMDA
Kentaro Azuma	MHLW
Hiroshi Ishikawa	Toshiba Medical Systems
Shigetaka Miura	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	BD Bioscience
Nicole Denjoy	COCIR
Jean Yves Carentz	Stryker
Participants: STUDY GROUP CHAIRS	**Organization**
Ginette Michaud	FDA
Isabelle Demade	European Commission

Participants: LIAISON BODIES AND OTHERS	Organization
Sanjay S Kumar - Observer	HSA
REGRETS	**Organization**
Rohan Hammett	TGA
Francois Simondet	Air Liqude Sante´ Inernational, EUROM VI (Medical Technology)

1. Welcome

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

The Chair welcomed the nomination of a new member to the SC from Europe – Francois Simondet who has been nominated in place of Carl Wallroth. The Chair also welcomed Dr Lillian Gill to her first GHTF SC meeting.

2. Approval of the Agenda

L. Kelly sought the agreement of members to add an additional item under Other Business to acknowledge the contributions of some past GHTF members. This was agreed.

Agreement was also sought to add an update report from the Rapporteur on medical device standards to the agenda. This was agreed.

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:

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

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

The Record of the March 2010 teleconference was accepted.

Action Items:

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

5. GMDN Update

J. Trunzo provided an update on the GMDN Agency. Both the Board of Trustees and the Policy Advisory Group (PAG) had met. AHWP have now attended one PAG meeting as an observer, and have also been invited to attend the Board of Trustees meeting to be held in Singapore later in the week. It was noted that getting the Board and PAG members in place has been a significant milestone in the GMDN Agency governance changes.

There had been enhancements to the GMDN database to provide for the increased number of terms (particularly the new IVD terms). Other key issues being progressed include work to secure a sustainable funding source for the Agency, ongoing discussions with ISTHDO in relation to possible future working arrangements; and the establishment of a back-up database server located outside of Oxford.

Given the absence of one of the European regulators from the meeting the Chair agreed that there would be an opportunity to re-consider this item later in the meeting at Item 9.10.

6. GHTF training strategy

Following on from previous SC teleconference discussions, it had been agreed that this item would be placed on the agenda for further discussion. At the March teleconference it had been agreed that outsourcing the training program would be the preferred option.

L. Kelly noted that he had received correspondence from the Regulatory Affairs Professionals Society (RAPS) indicating their interest in working closely with GHTF as a training partner. He also noted that AHWP had expressed interest in collaborating with GHTF in relation to training.

There was a discussion by the SC in relation to member views about outsourcing, with some members not supportive of outsourcing to other organisations on a commercial basis. Views were also expressed about the importance of GHTF maintaining control of training materials.

The SC endorsed its earlier decision to use external training bodies to provide training. Initially it was agreed that RAPS and MTLI would be approached, although there may be other bodies used in the future. The next step will be to determine how training will be managed within GHTF – for example, whether the secretariat will manage the training requests initially or whether a subcommittee will be required. It was also agreed that a possible website statement in relation to GHTF's approach to training would be drafted by the Secretariat for consideration.

The SC agreed the Chair will contact AHWP indicating GHTF's interest in working with them collaboratively in relation to training. It was also agreed that the Chair will signal to RAPS and MTLI that GHTF is interested in receiving approaches/requests for collaborative training opportunities through the Chair. It was agreed that any future approaches from other organisations proposing training collaboration would also be duly considered on a case by case basis.

It was noted that if training proposals from any of these organisations relate to training based on existing GHTF documents, endorsement of the proposals would be quite simple and, where possible, progressed by the Chair/Secretariat. However, where there are issues or decisions that may be contentious then the Steering Committee would be consulted.

It was agreed that NCAR training would continue to be progressed separately from other training.

Action Item:

- L. Kelly to contact MTLI, RAPS and AHWP indicating the GHTF's interest in collaborative training opportunities.
- Secretariat to draft a training position statement for GHTF website.
- Secretariat to circulate to SC members copies of historical documents prepared in relation to the identification of appropriate training bodies.

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

Australia

L.Kelly provided an update from the perspective of the Australian regulator, the Therapeutic Goods Administration (TGA). Items covered included the organisational restructure that will take affect in the TGA from 1 July 2010 and which will see a structural separation of pre-and post-market activities; an update on the recent Australian Government review of Health Technology Assessment in Australia, which is likely to impact on existing regulatory approaches in Australia; outlook and priorities for 2010-11, including the introduction of regulatory frameworks for IVDs and biologicals; and an update on NCAR from the Australian secretariat.

Europe

L. Selles provided an update on develoments in Europe from a regulatory perspective. Points covered included moving responsibility for medical devices to the Health and Consumers

portfolio and the appointment of a new commissioner; the mandating of the use of Eudamed for EU member states from 1 May 2011; work being undertaken in relation to reuse of single use devices, with a report due to the Commission in September 2010; as well as an update on proposals to update and merge some Directives.

Japan

K. Azuma provided an update on Japan. Points covered included an update on progress with the Action Program commenced in 2008; the scheduled signing of a confidentiality agreement with Singapore; MHLW's becoming a new member of APEC LSIF RHSC; as well as MHLW's proposal to RHSC on medical device training courses that will likely take place in Korea next year, funded by APEC.

United States

L. Gill provided an update from the United States regulator perspective. She provided an outline of the FDA's international regulatory cooperation, and the continued positive enforcement of cooperation between the FDA and other key regulatory partners to promote and protect public health; the strategic priorities for the CDRH in 2010; and outlined progress with a number of current initiatives, including the work to strengthen the 510(k) process, and the enhancement of transparency within CDRH.

8. Study Group Items

8.1 Study Group 1

G. Michaud presented a detailed update (by telephone) on the work of SG1. The report updated members on the key issues of the SG1 and IVD Subgroup work plan; SG1's liaison activities with HL-7; as well as collaboration activities with AHWP, Latin America and the Caribbean.

As the outgoing SG1 Chair, G. Michaud acknowledged the committed work of SG1 members and thanked them for their support during her time as Chair.

L. Kelly, on behalf of the SC thanked Ginette for her significant contribution to the work of SG1. He noted that since his involvement in GHTF it was evident that the work being undertaken by SG1 was of a high standard.

A brief discussion followed on the issues raised by the SG1 Chair in relation to looking for ways to strengthen the GHTF contribution in Latin America. It was noted that there had been contact made previously with PAHO in relation to possible liaison.

Action Item:

- M. Limoli agreed to follow-up the previous approach to PAHO in relation to establishing liaison with GHTF.

8.2 Study Group 2

I. Demade presented an update report (by telephone) on the work of SG2. She noted that SG2 was waiting on a membership nomination from Asia. The key achievements of the SG for 2009 were noted – that is, improved guidance on the NCAR Exchange Programme and the establishment of closer links with the Asian Harmonization Working Party's Working Group 2. The update included an update on work in progress and identified a possible New Work Item on which the SG sought SC guidance.

In relation to the proposal to undertake a review of N57R8:2006, the SC asked for a New Work Item proposal to be submitted for its consideration. In relation to the proposal to develop a SG2 training document, I. Demade was asked to forward a copy of the draft training document in its current form to enable the SC to consider it in light of its broader discussions on GHTF training issues.

Action Item:

- I. Demade to submit, on behalf of SG2, a New Work Item in relation to a N57R8:2006 review, for SC consideration.
- I. Demade to provide SC (via Secretariat) a copy of the draft SG2 training document to enable consideration by the SC at its July teleconference.

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

There was no written update provided for SG4. L. Kelly indicated that SG4 had met in early April to review comments on their draft document. They are continuing to review comments received and will provide an update at the next teleconference.

8.5 Study Group 5

S. Ludgate provided an update report on the work of SG5. The report was noted by the SC.

8.6 Study Group Chairs – SG1 replacement Chair

L. Kelly advised SC members that G. Michaud had tendered her resignation as Chair of SG1. The SC paid tribute to the outstanding contribution made by Ginette during her time with GHTF. There was a closed session to discuss options for a replacement.

Action Items:

- L. Kelly to write to regulators seeking nominations and views in relation to the appointment of a new SG1 Chair.

9. Ad Hoc Working Group Items

9.1 Counterfeit Medical Devices/Products

M. Limoli provided a brief update. She noted that the WHO was accepting comments on a draft document, *Draft Survey on National Legislation on Counterfeit Medicines*. She also noted that the Council of Europe is negotiating a conference on counterfeit pharmaceuticals, including medical devices. She offered to provide further information about the conference on request.

9.2 Global Model AHWG Update

J. Brinch presented, on behalf of the AHWG, an update on the work to define the GHTF Medical Device Regulation Model. He noted that since the Vancouver meeting some constructive feedback had been received. The AHWG is currently looking to consolidate comments, with the current timeframe aiming to finalise the task for SC consideration at its November 2010 meeting.

J. Brinch highlighted the key challenges for the AHWG in completing this task. These included the demonstration of interactions between the elements of the model; identification of weaknesses and gaps and how to address them; and the level of inclusion of guidance to the implementation of regulations – noting that the current intention was to exclude implementation guidance.

In relation to the interactions between individual elements, the SC recognised this as an important element of the work and asked that as a minimum the AHWG look to include at least a list or summary of interactions between the elements of the model, which could be enhanced at a future time. The SC asked that the guideline document review be a later piece of work, as it is not considered critical to the delivery of this work. It was agreed that the identification of weakness and gaps is not critical and the inclusion of a statement identifying what has been included in this initial stage would serve to clarify the scope. The Chair indicated that it may also be useful for the AHWG to prepare a future directions document on this task for consideration by the SC.

The significant contribution made by Tim Ulatowski was acknowledged by the SC in leading this work. It was agreed that J. Brinch undertake the role of chair of this Group. It was noted that the FDA membership at this stage remains open.

Action Items:

- AHWG to present its work to the SC at its November 2010 meeting.

9.3 No Item

9.4 'ISO 13485' update

A very early draft document had been circulated to SC members ahead of the meeting.
M. Neumann provided an update for the SC, and sought guidance on how best to progress the matter. The concern is that the current ISO 13485 does not reflect the changes that have

occurred around the world and that there is an urgent need for more specificity in the Standard. It was agreed that without encouragement the Standard is unlikely to be revised until at least 2015. Although there was expressed a strong concern on expanding the scope of the standard from QMS to product review, the SC agreed that a proactive approach is needed to seek an earlier update for ISO 13485.

The SC asked that M. Neumann liaise with Study Group Chairs to seek their input and views on progressing an earlier update. The matter will then be reconsidered by the SC about how best to progress the matter with ISO to encourage revision of ISO 13485 as soon as possible.

Action Item:

- SC members to provide comments on the draft document to M. Neumann.
- M. Neumann will then liaise with Study Group Chairs and report back to the SC before taking further action.

9.5 Unique Device Identifiers AHWG update

A verbal update was provided by L. Selles. At the Vancouver meeting it had been agreed that the AHWG would seek comments on its paper until 31 March 2010. Approximately 45 comments were received. He noted that work was underway to consolidate comments. The scheduled April meeting had progressed with limited attendance due to extensive airline disruptions. A further meeting is scheduled for early June. The SC agreed that, due to the exceptional circumstances that had delayed progress, the work timing be extended until the November 2010 meeting. It was noted that an update would also be provided at the July teleconference.

9.6 Software AHWG update

L. Kelly reported that correspondence had been received from S. Eagles (Co-Chair AAMI Software Committee) and B. Fitzgerald (GHTF Software AHWG) seeking an indication as to whether the SC intends to progress a recommendation to ask ISO/TC210 to develop an internationally based technical report on the validation of software used for the production and service of medical devices. AAMI is keen to progress this issue and will do so independently if GHTF is not ready to do so. SG3 had previously been undertaking work with TC210, however, this had been put on hold while the MoU with ISO was negotiated and SG3 progressed its work program.

There was a discussion as to whether the SC would like this work to be re-energised and if so whether it would be best progressed via SG3 or via a new AHWG, and whether a partnership arrangement is the best mechanism.

It was agreed that the SC would respond to AAMI signalling a positive intention to progress the previous recommendation, along the lines outlined in their correspondence.

Action Item:

- SC Chair to reply to S. Eagles signalling that the GHTF wishes to proceed with the earlier recommendation and indicating support for the development of a technical report as outlined in their correspondence.

9.7 Combination Devices AHWG update

L. Kelly reported that the work of the AHWG had been closed off previously by the SC. He reported that a summary table had been developed bringing together an overview of GHTF member regulation of combination products that had been referred to the Heads of Agencies (HoA) forum. Dr Kelly reported that a HoA working group had been established, including regulators of medicines, medical device and biologicals, which met in February in the United States. Subsequent to this meeting the table had been amended to include medicines and biologicals and work is now progressing under the wider regulatory banner. The issue will again be considered by HoAs at their next meeting in October 2010. He indicated that once HoAs are happy with the outcome of their considerations, there will be an opportunity for industry representatives to contribute and a proposal progressed.

9.8 Regulatory Change Management update

There was no update on this issue

9.9 Standards Rapporteur update report

A detailed update report was submitted by C. Wallroth, who had undertaken the role of Standards Rapporteur since 2006. His report identified 5 recommendations relating to the future progress of standards work within GHTF. This report was received late and was therefore not distributed to SC members prior to the meeting. The update report was presented at the meeting by N. Denjoy.

The presentation sought direction from the SC in 4 key areas:

- In relation to the nomination of new Rapporteur, the SC agreed that the role should continue. The nomination of N. Denjoy to undertake this role was welcomed and accepted by the SC. The SC asked that Nicole prepare a proposal for consideration at the July teleconference in relation to a possible strengthened mandate for the Rapporteur.
- In relation to the suggestion of establishing a Standards AHWG, it was agreed that SC members would forward input/comments on this suggestion to N. Denjoy to help inform the development of her proposal and its scope.
- In relation to the concept of creating an Annex to document reference to the Essential Principles (EPs), a concern was expressed by one country which has already developed such an Annex. Due to the lateness of the paper SC members required time to consider the proposal and reflect before deciding a position.
- In relation to the proposal to establish an MoU with HL7, the SC agreed that an invitation would be extended for a representative of HL7 to attend the November 2010 SC meeting to provide a presentation on the Regulatory Product Submission.

Action Items:

- Secretariat to distribute C. Wallroth report to SC members after meeting.
- N. Denjoy to prepare a proposal on the mandate and scope of the Standards Rapporteur for the July teleconference.
- SC members to provide comments/input to N. Denjoy in relation to scope and the possible establishment of a Standards AHWG, and also in relation to the concept of creating an Annex to document reference to EPs.
- L. Kelly to invite a HL7 representative to present on the Regulatory Product Submission at the November 2010 SC meeting.

9.10 <u>GMDN update continued</u> (discussion continued from Item 5)

Discussion in relation to GMDN had been deferred from earlier in the meeting at item 5 due the absence of one SC member during the earlier discussion. J. Trunzo provided a brief overview of her earlier report.

L. Kelly indicated that he had been asked by Susanne Hoeke of the European Commission to put to the SC the proposal of jointly developing a paper outlining the use of GMDN by regulators. The SC was asked whether they would like to endorse the development of such a paper by the Policy Advisory Group of the GMDN Agency. There was a discussion as to whether a decision by the SC to endorse such a piece of work would signal to the GMDN Agency that it is supportive of its current governance structure. Some SC members expressed a strong position that if GMDN Agency did not move to a more sustainable governance position then the GMDN would no longer be used by some members.

Action Items:

- L. Kelly to circulate the draft paper to the SC for discussion at the July teleconference.

10. Strategic Directions Planning Session – Discussions re Future Directions and Priorities

The morning of Day 3 of the SC meeting was dedicated to general discussions about the future strategic directions of GHTF. This was a closed session.

Action Items:

- Australia and Japan as the current regional Chairs agreed to produce a further discussion document by the end of 2010 based on SC discussions. It was agreed that this paper be used to seek HoA endorsement of future directions.

Other Business

11. Relations with Regional Groups and Other Interested Parties (Including Requests for Training)

Discussion on this item was included in the Strategic Directions discussion.

Action Item:

- The SC agreed there was a need to develop a strategy for how best to manage training requests and outcomes, including the possibility of making use of the experience of past SC members.

12. Procedural Issue: Format of Presentation of Papers to Steering Committee

The SC considered a proposal that a one-page cover page be included when Ad Hoc Working Groups or Study Groups forward papers to the SC for consideration. M. Gropp spoke to this proposal. It was agreed that such a process would enable SC members to quickly note whether the paper before them was a new issue or was a revised version as well as provide a brief history to the issue. It was agreed to implement the process of SG Chairs and AHWG Chairs completing the cover page when submitting documents for consideration. It was also agreed that the process would be used when New Work Items are submitted to the SC.

Action Item:

- Secretariat to prepare a draft template cover page for comment by SC members

13. Any Other Business

Recognition of individual contributors

The SC moved a vote of thanks to three key contributors to the work of GHTF of many years. These were Tim Ulatowski of the USFDA; Carl Wallroth representing European Industry; and Ginette Michaud of the USFDA. These individuals were applauded by the Steering Committee for their dedicated commitment to leading and furthering the work of GHTF.

Asian Harmonization Working Party (AHWP)

Action Item:

- GHTF Chair to remind AHWP that they would be welcome to seek regional membership of GHTF.

GHTF website

Chair advised that the Secretariat had approached Study Group Chairs for updated information for the website.

Action Item:

Secretariat to remind SGs and AHWGs to provide updated website information.

14. Upcoming Meetings

Teleconferences: 9 July 2010
27 August 2010
11 March 2011

Face-to-Face meetings: 2-4 November 2010 (Sydney)
11-13 May or 23-25 May 2011 (Australia – possibly Brisbane)

Action Items:

- SC members to advise suitability of 11 March 2011 for teleconference.
- Chair to confirm date and country of May 2011 face-to-face meeting.

Joint meeting of the Asian Harmonisation Working Party Technical Committee (AHWPTC) and the Steering Committee of the Global Harmonization Task Force

The final afternoon of the SC meeting took the form of an inaugural joint meeting of the Asian harmonization Working Party Technical Committee (AHWPTC) and the Steering Committee of the Global Harmonization Task Force.