Final Record of Discussions
GHTF STEERING COMMITTEE MEETING
10-12 MAY 2009
Toronto, Ontario, Canada

Participants: CANADA	Organization
Roland Rotter – Chair	Health Canada
Stephen Dibert – Vice Chair	MEDEC
Sabah Khan - Secretariat	Health Canada
Monique Chaine – Secretariat	Health Canada
Participants: UNITED STATES	**Organization**
Timothy Ulatowski	FDA
Gail Costello	FDA
Michelle Limoli	FDA
Janet Trunzo	AdvaMed
Michael Gropp	Medtronic
Elisabeth George (for Terrence Sweeney)	Philips Medical System
Participants: JAPAN	**Organization**
Hiroshi Yaginuma	MHLW
Hiroshi Ishikawa	Toshiba Medical Systems
Shigetaka Miura	Sakura Seiki
Participants: AUSTRALIA	**Organization**
Larry Kelly	TGA
Anne Trimmer	MTAA
Johan Brinch	Cochlear Limited
Participants: EUROPE	**Organization**
Laurent Sellès	European Commission
Matthias Neumann	Federal Ministry of Health -Germany
Giuseppe Ruocco	Ministry of Health-Italy
Jos Kraus	Health Care Inspectorate The Netherlands
Joanna Kilkowska	Medical Devices Department- Poland
Brian R. Matthews	Alcon Laboratories
Christine Tarrajat	EDMA
Carl F. Wallroth	Dräger Medical AG & Co. KGaA
Nicole Denjoy	COCIR
Jean Yves Carentz	Stryker
Participants: STUDY GROUP CHAIRS	**Organization**
Ginette Michaud	FDA
Isabelle Demade	European Commission
Egan Cobbold	Health Canada
Jan Welch	FDA
Susanne Ludgate	MHRA

Participants: LIAISON BODIES AND OTHERS	Organization
Kevin McKinley	ISO
Lindsay Tao	AHWP
Antonio Hernandez	PAHO/LAWHP
Susan Meadows – Observer	FDA
Supriya Sharma – Observer	Health Canada
Dan Schultz	ASTM
Ulrike Kreysa	GS1
Robert Hankin	HIBCC
REGRETS	Organization
Rohan Hammett	TGA
Tomiko Tawaragi	MHLW
Terrence Sweeney	Philips Medical System

Welcome and Approval of Agenda

R. Rotter and S. Dibert welcomed all members to the Steering Committee (SC) meeting.

The Agenda was approved, with the recommendation that the discussion on item 6.2 be combined with item 5.2.

WHO representative B. Fahlgren requested the opportunity to observe some discussion items via teleconference. Members of the Steering Committee discussed and determined that this would be acceptable. **Note** Representative from WHO was unable to participate due to conflicting engagements.

The Chair welcomed the new members: N. Denjoy, J. Kilkowska and J. Carentz, and thanked the retired or retiring members of the Steering Committee: W. Schoenbuehler (retired);
B. R. Matthews (final meeting); C. Tarrajat (final meeting); and J. Kraus (retiring Nov 09). All were thanked for their work on the GHTF and were wished well in their future endeavours.

Update Steering Committee Membership List and Contact Details

Action Items:
- Secretariat to contact T. Hancox for additional information on ISO list he provided.
- Members of the Steering Committee are to provide feedback to S. Dibert with regards to the suggestion of a group breakfast for the next SC meeting in Vancouver.

SC members were asked to update the list and return the document with any changes to the Secretariat. The updated list will be distributed to the members via email for final verification and will then be posted to the GHTF website.

Summary Records from the 15th Steering Committee Meeting

The action items from the previous Record of Discussions were reviewed. There were several items that required some follow-up by the Secretariat and it was suggested to include the names of participants who joined via teleconference to the attendance list.

The Record of Discussions was approved, and will be posted on the GHTF website.

Discussion of Process Improvement Draft Document/ Maintenance Mode

The focus of this work is to improve GHTF's efficiency and streamline its functions.
A. Trimmer provided background information on the AHWG on Process Improvement and outlined that the main goal was process development by examining the Study Groups in which some concerns were raised of how the Study Groups may re-invent themselves. The AHWG also looked at business rules and performance criteria and longer term issues such as the future of GHTF.

The discussion proceeded by looking at the recommendations in the order of the document. Some of the recommendations were well supported by the Steering Committee while others brought about further discussion and a lack of consensus.

There was much discussion on the issue of creating a maintenance team for the review of documents and the future of Study Groups. Timelines for Study Group revision of documents were also discussed. It was felt that perhaps finite timelines should be decided for the revisions reducing the amount of meetings and travel.

To address the issue of ongoing maintenance of documents, the AHWG put forward three options for the Steering Committee to consider. No consensus was reached on the three options and a fourth option was developed. Under this fourth option, Study Groups continue to work on tasks assigned to them by the Steering Committee and that it will determine if new work is to be assigned to a Study Group. However, once all the assigned work is completed, the Study Group would disband under the Maintenance Mode provisions, but 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 or work on new issues as part of an AHWG. .

A. Trimmer reviewed the various other recommendations the AHWG drafted in the document and these recommendations were all approved by the Steering Committee with some minor changes. Under section 2.2 Resources for SC and SGs, recommendations 'a' and 'e' were removed from the approval process to a later date for discussion. Training recommendations were also removed as they are addressed by another group. Also, the last set of

recommendations (page 10 of Process Improvement document) was deferred to after the Conference as well.

Action Items:
- AHWG on Process Improvement to revise document and present at the July 2009 teleconference.

Counterfeit Medical Devices/Products

The draft legislation document, produced by WHO, was revised. It now includes medical devices. It was circulated to members and they were asked to send any comments with respect to the medical devices portion to Konstantin Keller at Konstantin.Keller@bmg.bund.de, the chair of the IMPACT Legislative Work Group and to copy M. Limoli.

Action Items:
- Steering Committee members to provide comments to Konstantin Keller and M. Limoli

Proposal for new work items: Guidance for Change Management

J. Brinch gave a presentation on the "Guidance for Change Management". The proposed guidance is not meant to address how change is managed but rather to clarify the Regulator and Manufacturer responsibilities when assessing changes (in device and/or QMS) using a risk-based and process-based model. The regulatory environment itself is becoming more complex, more global and though there are some models already in existence, there are no global models to-date. It is becoming increasingly complex as more and more countries regulate therefore a global model makes a logical next step. The recommendation is that an *ad hoc* working group (AHWG) be created for a 24 month duration

Members agreed that this is an excellent corollary to the model document and support the creation of an AHWG with a focus on finer details as too broad a mandate could lead to confusion. It was stated that most jurisdictions already have documents available on Change Management, so J. Brinch stated that the AHWG could examine these documents to create linkages between them so the dynamics of the model can be fully understood. Reviewing the documents and identifying gaps in order to create a new document would bring it all together.

It was proposed and accepted to set up an initial AHWG, a small core group to look at the necessary scope of the document which can be expanded once the scope and needs of assessment are established. Nominations should be sent to the secretariat in the next 3 weeks, no later than May 29th, 2009. And a proposal is to be presented to the SC at the September 2009 teleconference.

Action Items:
- Nominations to be sent to the Secretariat by May 29th, 2009.
- AHWG on Change Management to provide recommendations at the September 2009 teleconference

Global Model AHWG Update

T. Ulatowski provided an overview of the Global Model document. The document still has the same fundamental format as the original however the intention/expectation was to try and keep it simple but instructive. Comments had been requested and he noted that very few comments have been received so far. At this time the AHWG would like direction from the SC on whether they should move forward with this draft, or whether they should continue to expand and re-edit the document.

Based on discussion, it was determined that this document will be posted to the GHTF website as a proposed document with a 4 month comment period.

Action Items:
- T. Ulatowski to forward revised and formatted document to Secretariat for posting as a proposed document.

Maintenance Mode AHWG Update

This discussion was incorporated into the Item 5.2 discussion.

Unique Device Identifiers AHWG Update

L. Selles presented a mid-term report from the AHWG on UDI. The main objective was to look at traceability, patient safety and technology neutrality. A questionnaire was sent out and analysis was completed in February 2009. From the analysis it was determined that there was a need for common definitions and a clear understanding of the function, and that a pragmatic approach should be taken.

The AHWG presented 20 recommendations to the SC requesting feedback/direction to move forward. There was some discussion on the format of the UDI label, post-market surveillance, and the SC's position on the GS1 and HIBCC standards. It was decided that the SC will need to look at the recommendations before discussing further; this item has been moved to the July, 2009 teleconference.

Action Items:
- Secretariat to distribute presentation to SC members, response and comments from SC by July 2009 teleconference.

Discussion of Software AHWG Recommendations

This item was deferred to the July Steering Committee teleconference.

Combination Devices AHWG Update

L. Kelly provided an update on the work of the AHWG on Combination Devices. At the February 2009 teleconference, the AHWG asked for permission to extend the life of the group. The Study Group Chairs were asked to review the documents and recommend changes that could be incorporated with respect to combination devices but were unable to do this until proper guidance was given on the definition of a "combination device".

Under the Terms of Reference, the AHWG was to explore the possibility of receiving input from other harmonization bodies besides medical devices however the US FDA raised concerns as to who the AHWG communicates with. It was felt that the AHWG should only be communicating with medical device industry which created a dilemma.

It was agreed that the AHWG should develop a principles-based document so that any guidance developed from it would be based on principles. A sub-group has created a guidance document but it's still in the working stages. As a next step, the AHWG is seeking agreement internally on a set of principles which will be forwarded to the SC for approval either at the July 2009 teleconference or November 2009 meeting in Vancouver.

There were two possible outcomes being discussed by the AHWG for presentation at the November SC meeting:
1) Review of existing GHTF documents will have been completed and an identification of the differences in the regulatory systems
2) There will be a document that describes the principles around which combination devices should be regulated and how documents will be created

Action Items:
- The AHWG on Combination Products will present the document of principles to the SC at the November 2009 SC Meeting

6.6 Training AHWG Update

R. Rotter was to coordinate the training committee initially, however, J. Welch has now agreed to lead the AHWG. J. Welch informed the Committee that L. Kessler had provided a list of specific action items in terms of working with AHWP. She explained that the AHWG is working with RAPS, MTLI and the Department of Commerce (US) to understand what training programs already exist.

The next step for this working group is to develop a possible plan on standardization of training. The goal is to present a set of proposals to the Steering Committee dealing with issues such as new technologies, a web-based interactive program, creation of certification and what type of certification as well as a timeframe. The intention is to present the proposal at the November 2009 meeting however the timeline may prove to be too short. The proposal may only be presented at the first teleconference following the November 2009 meeting.

Action Items:
- AHWG on Training to present a set of proposals to the SC at the November 2009 meeting.

Study Group Updates

Study Group 1

G. Michaud presented an update on the work of SG1 covering 3 main areas: the work plan, the membership expansion and documents for advancement. She outlined the work plan and noted the two guidelines requiring approval for advancement as well as the documents coming up for revision. There was some discussion on the need for revision and how often it is required. She also mentioned that SG1 membership expansion included a member of the AHWP. Under the AHWP's new leadership they are becoming more active and creating technical groups and working groups that parallel GHTF's Study Groups and there is potential for bi-directional impact that will lead to greater convergence. In terms of adding a Latin American delegation to the membership, a meeting was recently held in Argentina where their participation was encouraged and there are early efforts by industry to establish a regional group for discussion of harmonization issues however their participation has not been finalized and regulators have not yet joined in the regional group. Finally, G. Michaud presented the two documents for advancement and both were approved by the Steering Committee.

Action Items:
- Secretariat to post SG1/N055:2009 for final document and SG1 (PD)/N063 as a proposed document to the website.

Study Group 2

I. Demade introduced herself as the new chair of Study Group 2. She outlined the on-going activities of the Study Group such as the pilot project on reporting of adverse events, a Memorandum of Understanding (MOU) being created between the Study Group and ISO TC 215 and revision of documents for NCAR's exchange programme. Two revised NCAR documents were distributed to the SC for comments for the July 2009 teleconference. She

provided an overview of the NCAR program and how it has evolved. She mentioned the increase in requests for training and will be working to upgrade and expand training materials and create a reserve list of potential trainers. She will be reporting to the AHWG on Training for approval.

She presented new work items for the Study Group which includes adverse event reporting for clinical investigations and will involve collaboration with Study Group 5 in a small task force if approved by the SC and also provided the Study Group's work plan.

There was some discussion on the scope of the Study Group expanding and the SC feels that a comparison of work against the existing mandate should be presented at the upcoming July 2009 teleconference. Members wished to emphasize that the AHWP's input could be very useful to the revision of the documents. I. Demade noted that she would submit the FDA Thailand letter requesting to join the NCAR program to the Chair for approval at the July 2009 teleconference.

Action Items:
- Timeline for the clinical investigations adverse event document to be provided at the July or September 2009 teleconference.
- Study Group to provide a comparison of work against the existing mandate.
- Comments on the N79-R10 NCAR Reporting and N38-R18 NCAR Application documents should be sent in advance to I. Demade and a decision will be made at the July 2009 teleconference
- Letter from FDA Thailand to be submitted to Chair and Steering Committee for approval at July 2009 teleconference.

Study Group 3

E. Cobbold presented an update on the work of SG3 outlining membership, the work plan, outlook and decisions.

He informed the Committee that Study Group 3 recently welcomed two new members from the AHWP, a member from the Saudi Arabia FDA and a member from Singapore.

The SG3 document N18 (corrective and preventative action) will be finalized this week and will then be sent internally for comment and will be put forward for approval as a proposed document by the SC at the November 2009 meeting. N19 on Quality Management System (QMS) deficiencies is at the stage where the Group is trying to harmonize how deficiencies in QMS are assessed in the different regions. Work has not yet begun but has a publication target of 2011.

He also presented other work items that the group is focusing on including collaboration with SG1 and SG4. He stated the need to continue to work with ISO TC 210 and TC 176. He also provided a timeline of work being done on ISO standards 13485 and 9001, its impact on the work of SG3 and he emphasized the importance of working together with ISO in modifying

these standards. SG3 is requesting a decision from the Steering Committee that would allow SG3 to initiate liaison with TC 176 on behalf of GHTF and to begin to create an MOU similar to that with TC 210. There was a discussion on what level the MOU should be established with ISO and further discussion revolved around the extensive timeline, progress of SG3 and resources it would require to keep up the work on these GHTF guidelines while ISO takes 10 years to revise their standards.   Members requested to see the presentation and defer a decision to the July 2009 teleconference.

Action Items:
- Secretariat to distribute SG3 presentation to SC for decision on liaison with ISO TC 176 at the July 2009 teleconference.
- E. Cobbold to forward N18 document to Secretariat for distribution and a decision at the November 2009 SC meeting.

Study Group 4

J. Welch was welcomed as the new Chair of SG4.

Three items were brought to the Steering Committee as an update. She stated that there was a debate on whether they should further supplement the auditing documents (parts 1,2,3) and it was decided to add part 4 and 5 to the auditing series. This will give auditors more advice from N30 on how to conduct an effective audit, synthesize the report and recommend corrective actions if any are deemed necessary. There were software comments from the AHWG where it was recommended to add software on the N30 document. Most of these comments have been accepted as well as most of the text from the AHWG. This was mainly to help clarify what software is being referred to in N30 so that the auditor understands the different subsets of software. N30 was finalized on May 10th, 2009 and will be sent to the Secretariat for distribution to the Steering Committee for decision at the July 2009 teleconference.

She informed the Committee that SG4 had started working with SG3 on their N17 document. It is unsure as to when the work will be completed, however a goal was set to send it forward for comment and approval at the September 2009 teleconference. Finally, the software comments from the AHWG were discussed and it was recommended to add software on the N30 document and most of the text from the AHWG was accepted. There was some clarification of the type of software being discussed so that the auditor understands the different subsets of software and this will be revised and sent out.

Action Items:
- None

Study Group 5

S. Ludgate presented an update on the work of SG5. Members were reminded of the role of SG5 and an outline of finalized documents was given to the Committee. The SG5 document N4 (Post-Market Clinical Follow-Up Studies) is currently posted for a 6 month consultation which started in March 2009. She presented the documents currently in progress. The group is aiming to finalize the document for the sub-group on IVD by June.

A document on adverse event reporting is about to begin. Feedback from industry indicated that there are different requirements in different countries. There is a document in association with SG2 that aims to bring those comments together. A SG5 teleconference is planned for June and a joint SG2/SG5 teleconference is planned for September 2009 with the intention to bring the document to the Steering Committee by year end. Beyond this, SG5 feels they will have completed their mandate and anticipate going into a type of maintenance mode which has yet to be outlined.

Action Items:
   - None

Cooperation With International Bodies

Asian Harmonization Working Party

L. Tao provided a brief introduction on the AHWP explaining the similarities of the organization with the GHTF. She outlined the AHWP organizational structure and goals for the next two years. Members were given an overview of past meetings and advised that the next AHWP meeting is to be held November 4-7th, 2009. She mentioned that some of the challenges they encounter is that many of their member economies are from developing and underdeveloped economies and they have emerging or developing/evolving regulatory systems making cost/resources an important issue.

She stated that the AHWP needs support from the GHTF involving closer communication and collaboration as well as recognizing the needs of the AHWP where implementation and training are concerned. R. Rotter informed the Steering Committee that there was a scheduled GMDN meeting with the Chair of AHWP at this meeting, but due to H1N1, many AHWP members were unable to attend and so the meeting has been rescheduled to a teleconference. The date has yet to be determined.

Action Items:
   - Secretariat will coordinate with AHWP to schedule a teleconference to discuss GMDN within the next few weeks.
   - Secretariat to distribute the AHWP presentation to the SC.

Latin American Harmonization Working Party

A. Hernandez outlined his presentation on the LAHWP. Members were given a quick update on the work accomplished in Latin America. He stated that membership has expanded from 4 to 16 countries that are working to implement medical device regulations. He presented some milestones reached including the PAHO directive council resolution on medical devices, Pan American Cooperation on Medical Equipment (PACME) meetings of regulatory bodies and that various GHTF Study Group final documents have been translated into Spanish and are being widely used in the development of medical device regulations with an emphasis on training similar to AHWP. He encouraged another visit by the GHTF Chair to Latin American countries to strengthen the cooperation and collaboration message and to push for the creation of the LAHWP as PAHO itself can only recommend the creation and cannot be more proactive in participation. He also outlined a number of challenges being faced by PAHO/LAHWP such as the high rotation of regulatory authorities and the financial limitations of the member countries to attend GHTF activities. Finally, he mentioned some opportunities and emphasized the need for advice and support from GHTF and AHWP to form and organize LAHWP.

Action Items:
- Secretariat to distribute the LAHWP presentation to the SC.

Policy on translation of GHTF guidance documents

M. Gropp stated that this issue was first brought to GHTF in 2007 when L. Kessler came to the Steering Committee seeking a consensus view on the policy of translation. A small group was developed to create a proposed guidance on this topic and came to the Steering Committee several times. There were some unforeseen delays and the January 2008 which reflects the comments from the SC prior to January 2008. New comments are being requested, this time including comments from PAHO and AHWP. There was general agreement that the GHTF should support all translations however a blanket statement should be made to state that the documents are not that of the GHTF. Links could be provided to these translations. M. Gropp stated that the original proposal on translation was that, if adopted, the policy document on translation would be incorporated in the GHTF Operating Rules guidance document. All members endorsed the document for incorporation into the operating rules.

Action Items:
- Policy on translation of GHTF guidance documents to be incorporated into the GHTF Operating Rules guidance document.

Main Developments for Liaison Bodies - Update

Product Improvement

C. Wallroth presented the 5th GHTF rapporteur report to GHTF on medical device standards developments. Due to unforseen circumstances, the report was not circulated to the SC in advance but will be distributed after the meeting.

He mentioned that a significant achievement in product improvement is that ASTM developed a high level document, the ASTM H57, which deals with inter-operability of medical devices covering technical aspects and containing three subparts. He also mentioned that the Europeans have created a task force dealing with inter-operability, the IC-60, which recognizes regulatory development. The GHTF could possibly create a regulatory guidance based on J. Brinch's presentation on change management. The report covers 2 aspects communicated from the IT domain. The issue of the transition period is a topic that has been discussed several times but will need to be revisited. The report's 2nd sentence is highlighted for the consideration of the Steering Committee demonstrating where there is potential action required.

Action Items:
  - Secretariat to distribute document on Product Improvement to the SC.

GSI Presentation

U. Kreysa presented an overview of GS1 providing a better understanding of GS1 in light of GMDN. The GS1 system has an integrated approach, using global standards that are open for use by anyone. The system was initially created for manufacturers but now serves associations, hospitals and regulatory bodies alike. She described GS1's work with CEN and ISO and their relationship.

There was some discussion on funding, governance, access to datapools and how the nomenclature of GMDN fit in with GS1. U. Kreysa explained that GS1 is open to working with GMDN on the UDI issue but it will be up to GMDN to address what standard to utilize.

Action Items
  - None.

HIBCC Presentation

R. Hankin provided introductory information on HIBCC to the SC. They are accredited by the ANSI and CEN and have established global offices. They are also recognized by ISO and work within ISO framework. Much of the medical device industry is labelling with HIBCC standards and they are actively working with FDA on UDI labelling.

He introduced the HIBCC standards emphasizing that both (HIBCC & GS1) standards contain the same information however HIBCC is an alphanumeric standard allowing for direct coding of product information whereas GS1 are all numeric codes. Finally, he outlined some goals that require consideration for harmonization to occur such as the adoption of a universal set of regulations. There was some discussion on HIBCC's role in the maintenance of databases and whether HIBCC is using specific nomenclature to manage the data. He also stated that it was not necessary to choose a standard because both contain the same information; therefore they can be contained in the same environment without causing conflict.

Action Items:
- None

Update of Main Developments in Founding Members Regulatory Systems

It was decided that Founding Members would submit their updates via email and they would be circulated to the SC to be discussed at the July 2009 teleconference.

Action Items:
- Regulators to submit their updates to the Secretariat for distribution to the SC by the July 2009 teleconference.

Upcoming GHTF Meetings (GHTF Conference)

The next SC meeting has been scheduled for November 10-12th, 2009 in Vancouver, Canada. The meeting location has yet to be determined.

L. Kelly, the next GHTF Chair has advised that the first SC meeting following the one in Vancouver will likely be May 9-11th, 2010 in Singapore and the second meeting is likely to be October 10-12th, 2010 in Sydney.

Action Items:
- Secretariat to distribute logistical information regarding SC meeting scheduled for 10-12 November 2009.