

**Draft Record of Discussions
GHTF STEERING COMMITTEE MEETING
10-12 NOVEMBER 2009
Vancouver, British Columbia, 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
Terrence Sweeney	Philips Medical System
Participants: JAPAN	Organization
Shinobu Uzu (for Hidehito Sekino)	MHLW
Kentaro Azuma	MHLW
Hiroshi Ishikawa	Toshiba Medical Systems
Shigetaka Miura	Sakura Seiki
Participants: AUSTRALIA	Organization
Larry Kelly	TGA
Rohan Hammett	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
Benny Ons	BD Bioscience
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
Carlos Arglebe (for Egan Cobbold)	Health Canada
Elisabeth George (for Jan Welch)	FDA
Susanne Ludgate	MHRA
Participants: LIAISON BODIES AND OTHERS	Organization
Tim Hancox	ISO
Lindsay Tao	AHWP
Joanna Koh	AHWP
Toshiyoshi Tominaga - observer	PMDA
Susan Meadows - Observer	FDA
Linda Martin	TGA
Mike Ward	Health Canada
REGRETS	Organization
Hedihito Sekino	MHLW
Carl Wallroth	IEC
Bjorn Fahlgren	WHO

Welcome and Approval of Agenda

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

The Agenda was approved.

The Chair welcomed the new members to the SC from Japan: K. Azuma,

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.

Summary Records from the 16th Steering Committee Meeting

The May 2009 Record of Discussion was reviewed. It was suggested that the wording under the “Process Improvement/Maintenance Mode” section be changed as some members felt it did not properly reflect the discussion. M. Neumann provided revised wording and after some further revision by the SC, the new wording was accepted and the record was approved.

The July 2009 and September 2009 teleconference minutes were reviewed and approved by the SC.

Action Item:

- The May 2009 Record of Discussions will be posted on the public GHTF website.
- The July and September 2009 teleconference Record of Discussions will be posted to the secure GHTF website.

GMDN Update

J. Trunzo provided an update on the GMDN Agency and new developments. She stated that the Board met in the first week of October and focused mainly on governance documents at that meeting. She mentioned that transparency was considered an important goal within the Agency. J. Trunzo was elected as the Chair of the Board of Trustees. A number of improvements were reported such as IT updates. This was a very complicated task. A candidate for the Secretary-General position was interviewed to handle day to day business and Mark Wasmuth has accepted the position and will be reporting to CEO, Maurice Freeman.

She stated that the Board is looking at a financial framework next week and will be examining sustainable funding options. Another teleconference is scheduled in December 2009 with a Board meeting planned for 2010.

J. Trunzo mentioned that after a meeting with the AHWP the week of November 2nd, 2009, the GMDN Agency sent a letter to the Chair of the AHWP requesting their involvement in the governance of the GMDN. There are openings on the Board of Trustees and the Policy Advisory Group (PAG). L. Tao stated that at the AHWP meeting, they made significant progress on nomenclature and have agreed on a statement to issue. She stated that AHWP supports a single nomenclature and supports GHTF but there is still some discussion to be had. She also stated that the nominations for the PAG are almost finalized and they will submit them shortly.

R. Rotter stated that he received a call from Andriana Velazquez Berumen from the WHO and she wanted to discuss nomenclature. R. Rotter stated that he will be involving J. Trunzo and L. Kelly into these discussions with WHO.

There was a discussion on the IT upgrades and J. Trunzo clarified that the upgrades were a one-time activity however resources necessary to maintain the system is more of a long-term process. There are currently two technical experts involved in updating the GMDN, more resources will likely be necessary as the work continues.

H. Ishikawa reported on the first PAG meeting that he attended. He provided positive feedback and stated that various discussions were held on transparency for accounting, the need for GMDN, funding and operations, promoting GMDN and training for regulators and industry. He informed the SC that the Chair of the PAG is S. Hoeke.

There was a discussion and the SC agreed to extend the following message to GMDN in the meeting minutes: “The SC welcomes progress toward implementation of a new GMDN governance system. There is a desire for a single worldwide nomenclature for medical device regulation purposes, preferably being GMDN and that the GHTF looks forward to learning more about GMDN discussions on funding.”

Action Items:

- R. Rotter to include J. Trunzo and L. Kelly on discussion with the WHO.

Process Improvement Document Update

A. Trimmer stated that any comments on the Operating Procedures document should be sent to her by December 15, 2009 so the document may be revised for approval at the February 2010 teleconference.

Action Items:

- Comments to be forwarded to A. Trimmer by December 15, 2009 on the revised Operating Procedures document (GHTF/SC-N3R11).

Roles and Responsibilities Document Update

A. Trimmer provided an update on the revisions made to the Roles and Responsibilities document based on comments received at the May 2009 SC meeting. The revised document adds the inclusion of a category for Regional Members which will enable the AHWP to apply to become a member. Any comments on the subsequent revision of this document (GHTF/SC-N2R12) to incorporate the process improvement changes should be sent to A. Trimmer by December 15, 2009.

A. Trimmer requested the SC for final approval of GHTF/SC-N2R11.

Action Items:

- Steering Committee members approved GHTF/SC-N2R11 with the minor changes.
- Secretariat to post the final document on the GHTF website.

Counterfeit Medical Devices/Products

M. Limoli provided a quick update on the topic. She stated that the WHO WG met to revise the Draft Principles and Elements for National Legislation Against Counterfeit Medical Products document so that it includes medical devices. The revised document will be on the site for comment until the end of the year the 20th of December, 2009. Comments should be sent Konstantin Keller, document and comment template can be found on the WHO website.

J. Kraus stated that the Council of Europe has accepted a convention on counterfeits: “Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health”. This convention means all 41 members accepted all kinds of regulations on counterfeit medical products. This has already taken place in Europe and all countries will support this document at the next WHO meeting.

Action Items:

- J. Kraus to forward the Council of Europe document to the Secretariat for distribution to the SC.
- Secretariat to distribute the IMPACT document to the SC as well.

ISO MOU Update

Further clarification of the role of the working group created to review the ISO MoU was requested. The wording of the document was considered important and it was confirmed that the document should state that GHTF will be able to interact with any technical committee (TC). It was agreed that the deadline on this MoU should be by the end of 2009. R. Rotter requested that T. Hancox provide the revised MoU so the working group may examine and review it further.

Action Items:

- T. Hancox or K. McKinley to provide revised MoU to R. Rotter to distribute to the WG
- Secretariat to forward the revised MoU to the WG
- Final MoU will be distributed to the SC for approval

Global Model AHWG Update

T. Ulatowski stated that the draft document was posted on the GHTF website for comments and that he received some significant comments. However, I. Demade had mentioned at the May 2009 SC meeting that she had comments but these were never provided to the working group. The WG will be reviewing the comments and making revisions to the document. He stated that the AHWG is looking at completing the revisions in three months to present at the February 2010 teleconference. However, depending on the extent of the revisions, a second posting may be required. L. Tao inquired on how the AHWP could contribute to the document and was advised to distribute the document to AHWP members for comments. T. Ulatowski will report on the progress of the document at the February 2010 teleconference and will consult with AHWP and other liaison bodies for their input. He requested a six month extension and it was approved by the SC. N. Denjoy stated that Europe will provide a nominee to the AHWG to replace J. Kraus.

Action Items:

- T. Ulatowski to work with AHWP and other liaison bodies on revisions to the document.
- T. Ulatowski to present the revised document to the SC at the February 2010 teleconference.
- European delegation to forward nominee to the AHWG to replace J. Kraus

Maintenance Mode AHWG Update

M. Neumann stated that no further progress was made with the AHWG since the May 2009 SC meeting. There was a brief discussion on what was truly required at this time, processes, how and when a SG should conclude its work, and whether an expert list should be created. As much of this discussion was a duplication of the May discussion it was determined that the AHWG had essentially covered all topics and that procedure was all that was left to create and that this should be added to the Roles and Responsibilities document as well as the Standard Operating Procedures document. R. Rotter thanked the Maintenance Mode AHWG for their work and disbanded the group. SC members were requested to send comments to A. Trimmer by December 15, 2009 on the suggested procedures for the maintenance of SG documents which is to be included in the constituent documents.

Action Items:

- SC to forward comments on maintenance mode to A. Trimmer by December 15, 2009

Unique Device Identifiers AHWG Update

L. Selles provided a brief background to the UDI initiative and how the AHWG was established at the October 2008 SC meeting in Ottawa. He presented a draft guidance document to the SC for comments and approval to post on the GHTF website for a 6 month comment period. The aim is to receive all comments by spring 2010 in order to synchronize with the US initiative. He discussed the comments received and proposed next steps for the UDI AHWG. There was a discussion on the need to address the UDI system vs. database and the need to have one global system. It was suggested that the document presented was not a guidance document just yet but rather a discussion document which should be posted for comments. The SC posed a list of questions to the AHWG to consider incorporating in the document dealing with the vision for the future, UDI database, implementation, the role, if any, of GHTF in the coordination of database, proposed lists of materials/allergens of concerns and the role of GHTF in establishing and maintaining this list. It was stated that GHTF could articulate the principles of a system, but each jurisdiction has a UDI database and the AHWG does not have the mandate to work on these issues so it's best to articulate just what the principles of the design of a database should be.

It was suggested to reduce the comment period from 6 months to 4 months which would align it better with the US FDA initiative. R. Rotter advised L. Selles to provide a revised document by the end of the meeting to approve as a discussion document with a 4 month comment period. A clear rationale should be provided and it should clearly state the expectations on where the comments are being sought.

L. Selles provided a revised cover page for the discussion paper and outlined the expectations of this consultation phase. There was a discussion on the questions he proposed and some suggestions were made for further clarification and revisions on the UDI database issue. It was suggested to separate the questions about UDI system and UDI database.

Also, there was a discussion on whether the mandate of the AHWG should be expanded to examine databases as well. It was decided that the AHWG mandate would remain *status quo* for the time being.

L. Selles presented another revised discussion paper, with questions divided in two parts. After some minor editorial changes, the document was approved by the SC to post as a discussion paper with a 4 month comment period.

Action Items:

- Secretariat to post the revised discussion document for a four month period
- After the consultation period, the SC will decide on whether the mandate of the AHWG should be expanded to include the UDI database issue

Software AHWG Update

R. Rotter stated that he received comments from the SGs, they accepted the recommendations by the AHWG and will implement these recommendations. He thanked the members of the AHWG for the work that was done and disbanded the AHWG.

Action Items:

- R. Rotter to send a note to the AHWG Chair and members.

Combination Devices AHWG Update

L. Kelly provided background information on the mandate given to the AHWG on combination devices and presented the group's final document. The AHWG tasked the SGs to examine their documents at which time a clear definition of a combination device was requested. The WG had compiled a table demonstrating the differences in how the various regulatory agencies handle combination devices. The table also showed the areas of harmonization. The AHWG also attempted some outreach to other areas of combination devices such as biologics, however in February of 2008 the US FDA sent a note to the GHTF cautioning that such outreach was premature.

The issue of combination products and harmonization was taken to the Heads of Agencies meeting in Ottawa in October 2009. R. Hammett briefly explained that the paper by the AHWG was discussed in the half day meeting on this topic with the HoA. There was general appreciation of the AHWG in articulating the current regulatory position from the device perspective on combination products. A lengthy discussion on the approach taken in different parts of the world took place. It was felt that given the diversity of approaches, it was not possible to move forward with a single harmonized approach. It was mentioned that Dr. Lumpkin would be producing a paper on the best way regulatory agencies can approach the combination products issues. There was a commitment from the Heads of Agency to come up with a plan in their jurisdictions, but that the GHTF should not move beyond the scope of the AHWG paper.

R. Rotter stated that the goal to bring this issue to senior level interest has been accomplished and the HoA will now move forward on this issue. He thanked the AHWG for its work and disbanded the group. L. Kelly stated that this situation should be clearly conveyed to the SGs.

Action Items:

- R. Rotter to send a note to the Chair for the AHWG
- L. Kelly to communicate the information from this discussion to the SG Chairs.

Training AHWG Update

M. Brady provided an update on the progress of the AHWG. She stated that the group met in July 2009 and then in Hong Kong last week and discussed issues that needed to be resolved before drafting a training document. She explained that there were several questions that were raised and needed SC direction. The group feels that there is a need for three levels of training: Basic, Intermediate to cover more specific items and advanced which could cover very specific requests. She put forward several requests to the SC:

- Can a SC coordinator be provided?
- A protected website to discuss training needs would be needed
- There is a need to know about funding sources to send trainers to sites.
- There is a need to know what type of training media is acceptable.
- What is the WG ability to partner with outside organizations?
- Is certification of trainers viewed as important by the GHTF? And what would this mean?

The original charter of the training group was questioned. Some believed that the original charter was to look at outside training partners to avoid burden on GHTF, to develop a curriculum and to look for training partners. M. Brady stated that this was not communicated with the AHWG. Background information on the AHWG should be located if possible. It was felt that most of the questions and concerns raised by the AHWG have already been addressed in previous meetings. It was requested that S. Meadows provide further information to the AHWG about the PBWorks secured website. J. Trunzo stated that two training partners (RAPs and MTLI) were identified with the FDA and this information was communicated to the previous Chair of the AHWG. The SC felt that the training AHWG mandate may need to be reviewed. Due to the change-over in members of the AHWG, the original mandate may have been misunderstood. R. Rotter and L. Kelly agreed to contact J. Welch in the next couple weeks and discuss the mandate of the AHWG and provide further direction.

Action Items:

- S. Meadows to provide secure website information to J. Welch
- R. Rotter and L. Kelly to contact J. Welch in the next two weeks to discuss the mandate of the training AHWG and provide further direction

Regulatory Change Management

J. Brinch provided background information on the regulatory change management working group. He proposed that a guidance document be created. It should look at how the regulatory oversight should be harmonized. The SC had agreed to this at the May 2009 SC meeting, however further clarity on a scope for the AHWG was required. The working group now has 6 members and after discussions within the group a proposed scope of work is being presented for

approval to the SC. R. Rotter suggested to include a member of AHWP into the AHWG. There was a discussion on the scope and it was felt that it was too general. The SC requested a revised scope be presented by the end of the meeting for approval.

J. Brinch presented a revised scope to the SC. Some discussion ensued, minor changes were made and the SC approved the scope. It was suggested that each jurisdiction be represented in the AHWG. It was also suggested that the AHWG be Chaired by a regulator. Gary Burgess of the Therapeutic Goods Administration of Australia was nominated to Chair the AHWG. The SC approved the scope and creation of the AHWG with a provision to include a disclaimer that each regulator is to make their own decisions and to exclude an examination of the regulatory approval process following changes.

Action Items:

- Each jurisdiction interested in participating in the AHWG to nominate a representative to the AHWG
- J. Brinch to invite AHWP to join the AHWG
- G. Burgess to assume position as Chair of the AHWG

Strategic Review Update

In July 2009, it was decided that the GHTF should conduct a strategic review that would optimize the internal workings of GHTF. The SC endorsed the need for a new strategic plan at its Toronto meeting when accepting the process improvement document. The SC also noted that the previous action plan covered the period 2007-2009 and that it was timely to review progress over that period. A. Trimmer proposed that at this stage, Australia would draft an initial paper for consideration, rather than forming an AHWG. The group would be tasked with coming up with a discussion paper for early next year and table a more definitive document at the next SC meeting in May 2010. R. Rotter suggested that Australia, Japan and AHWP work on this document as the previous action plan of 2007 was a North American initiative. There was agreement that it was necessary to examine the future direction of GHTF and it was decided to have an extended discussion on this item at the May 2010 SC meeting. In the meantime, L. Kelly and A. Trimmer will work together to produce the initial paper.

Action Items:

- A. Trimmer and L. Kelly to produce an initial paper on the next steps of Strategic Review at the February 2010 teleconference and after discussion and input from Japan and AHWP, table a more developed document at the May 2010 SC meeting.
- An extended session to be held at the May 2010 SC meeting to discuss the strategic direction of GHTF

Glossary of Terms Update

H. Ishikawa provided some background material on the Glossary of Terms document. He presented a guideline, discussed naming conventions and timelines suggesting that the glossary be updated after face to face meetings only and not after teleconferences. He developed a flowchart demonstrating the process regarding the addition of new terms and mentioned that a Standard Operating Procedures manual would be key to maintaining an appropriate Glossary. It was suggested to send the instructions to A. Trimmer to be incorporated into the operating procedures document. It was suggested that the Secretariat be responsible for maintaining the Glossary.

Action Items:

- H. Ishikawa to forward the guidelines to A. Trimmer to include into the operating procedures document.

Study Group Updates

Study Group 1

G. Michaud presented an update on the work of SG1 covering 3 main areas: the Study Group work plan, the SG1-AHWP collaboration and challenges facing SG1. Five guidelines are undergoing revision. These revisions require considerable time and attention because of the growing collection of GHTF guidelines and the need to ensure clarity and consistency between documents.

G. Michaud informed the Committee that AHWP was invited to increase its membership to a total of four participants on SG1 in recognition of the large number of countries and the vast population represented by the organization. Beginning in July 2009, SG1 and AHWP have agreed to hold regular communications in order to stay abreast of developments in each organization, and to explore opportunities for harmonization.

The Chairwoman outlines some of the challenges facing SG1 including the difficulty of maintaining the relevance of the Study Group's documents in the context of an ever increasing diversity of regulatory frameworks. She added that efforts in support of Latin American participation in SG1 are continuing. However, progress is hampered by the absence of regional organizations that speak for the regulators and the regulated industry in Latin America.

There was a question regarding how SG1 identifies documents for revision. Documents are revised periodically, consistent with the Steering Committee's guidelines (GHTF/SC-N3R10 GHTF Operating Procedures). Guidelines are first circulated for review and comment among SG1 members and individuals listed on the SG1 Communications Database. Comments resulting from this consultation form the basis of any revisions, which could be minor or extensive, depending on the document. G. Michaud emphasized that as the number of GHTF guidelines grow, greater attention must be given to revisions because of overlapping content and

potential discrepancies between guidelines. A recent example is that of the Final SG1 “Labelling” guideline and the newly drafted guideline on Unique Device Identifiers. G. Michaud mentioned that coordination on labelling content with respect to UDI will be needed. L. Sellès stated that he is willing to engage in necessary clarifications so the documents are more aligned in regards to labelling.

Action Items:

- G. Michaud to contact L. Selles to discuss the UDI issues.

Study Group 2

I. Demade stated that since the May 2009 SC meeting, SG2 has had two documents approved: revised N79 and N38. She outlined the progress on new work items and discussed the proposed document N87. There were questions surrounding the N87 document and its interoperability with HL7. A lack of resources has currently delayed this aspect of the project. Members agreed that SG2 should work up a rationale for expanding the scope of the N87 document.

She updated the Committee on the NCAR exchange programme. At the May 2009 meeting, the SC endorsed the Thai request to join the programme and they are now a member. A new application from the Chinese SFDA has been received; however it’s unclear in what capacity the Chinese SFDA would like to participate in the NCAR programme. I. Demade will contact Chinese SFDA to clarify their request. In the meantime, she recommends the SC to endorse the SFDA request and SG2 will then decide on trainers (Australia, US FDA and Japan). The SC supported the request from SFDA but requested I. Demade clarify in what capacity they would like to join.

There was a discussion on SG2’s experience with countries reporting on the NCAR programme. Thus far only Saudi Arabia has contributed to the reporting. Other countries such as Cuba, Hong Kong and Thailand have not yet submitted any reports. A review will be necessary to examine the achievements of the NCAR program as well as review how applicants are evaluated and how the training is conducted. She stated that in a meeting with WG2 of AHWP, similar concerns were raised with their SAD system.

Action Items:

- Secretariat to forward SG2 meeting updates to the SC
- I. Demade to clarify SFDA request to join the NCAR program; SC approved request to initiate the process of welcoming China to the NCAR program
- Secretariat to remove N87 document from website
- I. Demade to provide a rationale for expanding the scope of the N87 document by the February 2010 teleconference.

Study Group 3

C. Arglebe presented an update on the work of SG3 outlining membership, the work plan and approval of the proposed N18 document. He mentioned that members met in September to finalize the N18 document and made significant progress on the N19 working draft. He outlined the next steps required for the N19 document with the goal of publishing the document in early 2011.

There was a discussion on the document and whether it was aligned with the work item proposal. The document seemed theoretical rather than practical. The proposed document N18 was approved with the comment that the SG must go back and review the work plan to ensure the document is better aligned with it.

There was a discussion on the number of face to face meetings and the SG was advised to reduce their current schedule of 3 meetings to 2 meetings. C. Arglebe stated that they are looking into new technologies and will revise the meeting plan for 2010. R. Rotter stated that E. Cobbold should provide the revised meeting schedule to the Secretariat before the February 2010 teleconference. Also, they were advised to update their work plan on the GHTF website.

M. Neuman questioned whether SG3 and GHTF should be waiting on the work of ISO TC 210 and its work on the 13485 standard or if GHTF should outline its position with SGs supporting such a project. It was decided that a small group of SC members would work with the SG Chairs to develop a scope and determine what type of role GHTF should be playing in ISO's development of these standards. S. Miura, M. Neuman and J. Kilkoskwa volunteered for this group and will work with the SG Chairs to provide a recommendation to the SC by the February 2010 teleconference. It was also emphasized that the SC should be well informed on what the SG's direction is and in turn SG3 should be communicating with regulators to determine what the founding members are seeking in regards to 9001 and 13485. There seems to be a disconnect and it's important that the SC know what concerns the SGs have for 9001 and 13485 revisions.

Action Items:

- N18 document approved to post as a proposed document with a 5 month comment period, however SG3 to determine whether the document is actually aligned with the work item proposal
- E. Cobbold to forward a revised meeting schedule for 2010 to the Secretariat before the February 2010 teleconference
- M. Neuman, J. Kilkowska, S. Miura to work with SG chairs to provide recommendations to the SC on concerns with ISO 13485/9001 by February 2010 teleconference

Study Group 4

E. George provided an update on the progress of SG4. She stated they have two documents currently under progress. The N83 document was reviewed at the last meeting and was posted in September 2009 on the website with a four month comment period. No substantial comments

have been received yet. The N30 document on Regulatory Auditing Strategy was posted in September 2009 as well with a two month comment period but so far no comments were received. The final document as per SG4's work plan is N84 which is up for approval by the SC at this meeting with a four month comment period. If the document is approved and posted, the SG plans to hold a meeting in late spring 2010 to discuss the 3 documents, but if comments are limited, then the discussions will be conducted electronically.

She stated that SG4 will update the work plan on the website as well.

The SC approved the proposed N84 document with a four month comment period.

Action Items:

- Secretariat to post N84 document as a proposed document with a four month comment period
- SG4 Chair to ensure cover sheet is revised to proposed document from working draft
- SG 4 to update work-plan on the website

Study Group 5

S. Ludgate presented an update on the work of SG5. She outlined the role and membership of the SG. SG5 just finished a two day meeting in Brussels and there are three documents under progress at the moment. She stated that the SG discussed the Clinical Investigations document in detail and have re-written the document. It will be submitted to the Secretariat in the next couple weeks. The third document involves working with SG2 on Adverse Incident Reporting. There is some work that still needs to be completed and a joint meeting with SG2 is scheduled for early next year.

Action Items:

- N1R8 and N2R8 documents to be forwarded to Secretariat for distribution in the next couple weeks.

Update of Main Developments for Liaison Bodies

International Organization for Standardization (ISO)

T. Hancox provided an update on new developments within ISO since K. McKinley presented to the SC in May 2009. He discussed the standards, work in progress and emerging areas such as traditional Chinese medicine. He explained the difference between a Technical Committee (TC) and a Project Committee (PC) which is created to produce a single production whereas a TC can go on to produce multiple standards. T. Hancox stressed that CASCO will be a major area of

collaboration in the future. He then outlined the purpose of the GHTF-ISO MoU. As mentioned earlier in the Record, the revised version from ISO was requested and will be sent to R. Rotter.

Action Items:

- T. Hancox to coordinate with K. McKinley and provide a revised MoU to R. Rotter for review and approval by the SC.

Asian Harmonization Working Party

J. Koh presented on the structure and membership of AHWP. She outlined the work being done by AHWP.

There was a discussion on membership flexibility in working groups and how they determine participation. Currently AHWP TOR states that the organization is open to any member and there has been a lot of interest from Latin American countries such as Chile to join AHWP. It was explained that Chile had common factors since there are challenges with creating a regulatory system and since LAHWP has not been created yet, AHWP decided to accept them. As for countries from the Middle East, AHWP is actively trying to engage them, so much so that the next meeting will be held in the Middle East.

J. Koh then presented a letter to the GHTF Chair from ACCSQ-MDPWG (ASEAN Consultative Committee on Standards and Quality - Medical Devices Product Working Group) to create a formal relationship between GHTF and the working group. R. Rotter stated that he will review the letter and will hold a discussion of the request at the February 2010 teleconference and will have a response by early March 2010 for Mr. Rahman (Chair of the MDPWG).

Action Items:

- R. Rotter to discuss liaison request between GHTF and ACCSQ received from AHWP at the next teleconference and to respond back by end of February or early March 2010.

International Electrotechnical Commission (IEC)

N. Denjoy stated that two additional documents (meeting reports of an IEC committee) along with C. Wallroth's Rapporteur Report were distributed to the SC by the Secretariat. Two specific matters were highlighted, an annex document referring to joint effort between IEC subcommittee and ISO 210 and that HL7's work on format and content of electronic regulatory submissions is potentially in conflict with ongoing work in these fields ISO and IEC as well as with that of GHTF. It was suggested that this is an area in need of establishing a working relationship with ISO TC 215 and HL7. There was a discussion and concerns were raised on the overlap between HL7 and ISO TC 215 and getting the SGs involved in this process to avoid any contradiction in electronic submissions. R. Rotter stated that the Secretariat will contact SG1 and SG2 to initiate contact with HL7 and to possibly use SG1's contact in HL7 to facilitate this

process. It was also suggested that R. Rotter indicate this is an area of interest in his response to ISO and to facilitate contact between HL7, ISO215 and SG1 and SG2.

C. Wallroth's report was accepted by the SC.

Action Items:

- Secretariat to contact SG1 and SG2 next week to initiate contact with HL7 and ISO TC 215 to discuss electronic submissions
- SG1 to facilitate contact with HL7
- R. Rotter to mention GHTF's interest in this area in his communication with ISO, and request ISO to facilitate contact between HL7, ISO TC 215 with SG1 and SG2

World Health Organization (WHO)

R. Rotter discussed the details of his teleconference with Adriana Velazquez Berumen from WHO. She stated that the MoU between the GHTF and WHO may be caught up in their legal department and she would follow up on this. They discussed GMDN and she requested R. Rotter to attend their meeting in Rio de Janeiro on Monday November 9, 2009. He was unable to attend. R. Rotter also informed the Committee that he was scheduled to meet with officials in Brazil and Mexico on behalf of GHTF and supported by the US Department of Commerce, however the meetings were cancelled last minute.

APEC LSIF Discussion

M. Ward provided the objectives of the presentation, an overview of APEC along with its structure and organization and background information on the APEC Life Science Innovation Forum along with its strategic plan. He stated that LSIF is well positioned to serve as an enabler of harmonization. He also discussed some of the challenges facing LSIF and discussed the role of the APEC Harmonization Centre (AHC). Finally he outlined the accomplishments of LSIF and some of the outstanding actions. He invited M. Limoli and H. Ishikawa to provide comments as well. M. Limoli stated that there is great collaboration between regulators and industry and would appreciate GHTF's endorsement and support. There was a discussion how the permanent secretariat will be funded and where it will be located. Also, R. Hammett stated that the TGA would like to be involved in the LSIF, however has not been invited yet.

Update of Main Developments in Founding Members Regulatory Systems

Australia

L. Kelly introduced Linda Martin as the new secretariat for GHTF once the Chair is transferred. He provided a current backdrop of changes within the TGA. He outlined the outcomes of those changes and stated that the transition required all sponsors of medical devices to transfer to the new set of regulations. The turnaround time of applications has been reduced significantly and the real benefit is that those resources can now be shifted to post-market programs. He stated that they have also had a look at the regulations and guidance's to determine where changes are required. The IVD regulatory framework is now well advanced and looking at implementation near next year and companies have 4 years to transition. The framework is heavily based on the GHTF framework. There was a discussion on the regulation of high risk IVD's and how the TGA will be regulating these devices.

Europe

L. Selles provided an update on the developments in Europe to the Committee. He informed the Committee that a new president has been elected for the next five years, Mr. Barroso. The Lisbon treaty will go into force on December 1, 2009. Also, there will be new commissioners, unsure of the timing of this so there may be possible reshuffling of portfolios. He stated that in his unit there will be two broadcasts: There will be single regulations for all devices and one for IVDs. On January 1, 2010, application of a new legalization process of marketing of products will come into effect (EU 765/2008 - setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93) that enters into force from 2010. This includes requirements for accreditation for conformity assessment bodies and is applicable to all sectors including medical devices. He stated that the Medical Device Directives contain provisions on a European databank for medical devices, which has been developed under the name Eudamed. The aim of Eudamed is to strengthen market surveillance and transparency in the field of medical devices. Initially Eudamed was only used by a few member states on a voluntary basis; however we are now getting closer to full Eudamed implementation with member states voting favourably. The use of Eudamed will be obligatory from May 2011 onwards. There is no direct new obligation for new manufacturers. It is not publicly accessible and will not replace national registration.

Japan

K. Azuma provided an update on Japan. He stated that PMDA established an office of international programs this year in order to strengthen international activities. MHLW/PMDA are actively working with industry to implement Action Program of Medical Device Review (issued December 2008). A confidentiality agreement between Health Canada and MHLW/PMDA was signed last month along with an agreement between EC and MHLW/PMDA. He discussed the new collaborative pilot program with the USFDA regarding collaborative consultation and review of premarketing applications in the cardiovascular field ("Harmonization by Doing").

United States

T. Ulatowski introduced the new Commissioner, Deputy Commissioner and acting CDRH Director. The new Commissioner set some action items that garnered some media attention. There are a number of items happening with the FDA. Health care initiative is at the forefront. Strengthening the FDA by aligning FDA resources and seeking new funding for our programs. Combination Devices are also being discussed and the use of ISO audits so there may be some significant changes on behalf of FDA on this issue. There is an initiative in the US on the Health Information Technology front and there are efforts and funding available for creation of this system which is being fast tracked due to a push by the government. He mentioned some notable actions such as the initiative on the regulation of tobacco, electronic medical device reports, 2nd year of electronic registration and a recent issue with some manufacturers that had devices containing titanium from certain sources.

Canada

R. Rotter outlined the drivers for various initiatives within Health Canada. Business modernization, International practices and harmonization, Departmental/Branch activities Auditor General of Canada and Evolving issues were the initiatives mentioned. He stated that the change of IT issues to Corporate was limited our ability for IT changes, however some changes such as information broadcasts to manufacturers are still being conducted. He discussed the performance targets for applications and even after process improvement, volumes are just increasing. He stated that Docubridge is not a high priority for the department so it's still pending. He briefly mentioned other areas of work such as the Sentinel network pilot (modelled after the USFDA), UDI, WHO's counterfeit devices, collaboration with CDRH and TGA such as the PMAP and exchange of our CMDCAS certificates. He also mentioned that Bill C51 should be tabled in parliament soon and will have a major effect on the Food and Drugs Act and some effect on device regulation. He discussed that the Auditor General of Canada has initiated a third audit of the Medical Devices Program. He also mentioned that the consultation documents for investigational testing should be out soon and this will align us with other jurisdictions and with drug clinical trials. He mentioned the ruling on single-use devices (SUDs) (provincial not federal, competence) and outlined some other evolving issues such as the registry of implanted devices, phthalates, drug quality assurance, combination devices, cost recover and software.

GHTF Rotation of Chair and Upcoming GHTF Meetings

R. Rotter thanked the SC members, SGs, guests and observers, co-Chair, Secretariat, MEDEC and S. Meadows for their work and support.

L. Selles and R. Rotter thanked J. Kraus for his contribution to the SC now that his term has been completed.

L. Kelly thanked R. Rotter, S. Dibert and MEDEC, and the Secretariat. He confirmed that the first SC meeting would be in Singapore from May 10-12, 2010, followed by a meeting in Sydney

from November 2-4, 2010. Teleconference dates have already been circulated. There is the possibility of a joint conference with AHWP but further discussions with AHWP will be needed.

Secretariat will give L. Martin a CD with all GHTF documentation at the end of the meeting and the official transfer will be done via teleconference.