Draft Record of Discussions
GHTF STEERING COMMITTEE MEETING
6-8 OCTOBER 2008
Ottawa, Ontario, Canada

Participants: CANADA
Roland Rotter – Chair
Stephen Dibert – Vice Chair
Jessica Dean - Secretariat
Lindsay Hardy – Secretariat
Participants: UNITED STATES
Larry Kessler (via teleconference)
Timothy Ulatowski
Gail Costello
Michelle Limoli
Janet Trunzo
Terrence Sweeney
Michael Gropp
Participants: JAPAN
Hiroshi Yaginuma
Shinobu Uzu
Hiroshi Ishikawa
Shigetaka Miura
Participants: AUSTRALIA
Rohan Hammett
Larry Kelly
Anne Trimmer
Johan Brinch
Participants: EUROPE
Laurent Sellès
Matthias Neumann
Giuseppe Ruocco
Jos Kraus
Brian R. Matthews
Christine Tarrajat
Carl F. Wallroth
Participants: STUDY GROUP CHAIRS
Ginette Michaud
Jorge Garcia (via teleconference)
Egan Cobbold
Tim Missios (via teleconference)

Greg LeBlanc (for Susanne Ludgate)
Participants: LIAISON BODIES
Tim Hancox (ISO)
Charles Sidebottom (IEC)

Welcome and Approval of Agenda

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

The agenda was approved, with two modifications. One item, Guidance on the Management of Process and Design Changes, was added to the agenda; one item, GHTF Approach to Controversial Chemicals, was removed.

There was a brief discussion surrounding the need to ensure document controls are in place, and, for future meetings, to ensure that documents and speakers linked to agenda items are clearly identified. Participants were also reminded that documents must be submitted to the Secretariat a minimum of eight weeks in advance of SC meetings or teleconferences to allow time for delegation consultations.

Update Steering Committee Membership List and Contact Details

A membership list was circulated and members indicated changes that will be made to the membership list posted on the GHTF website.

Summary Records from the 14th Steering Committee Meeting

The action items from the previous Record of Discussions were reviewed; it was indicated that one action item (Copyright) had not been flagged, and no draft statement had been developed to-date.

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

Global Medical Device Nomenclature

L. Kessler indicated that he had received a revised version of the GMDN Agency governance document; the document had not been circulated to other GHTF members. He stated that the

document is a positive move forward, and involves, as a first step, re-starting the Maintenance Agency Policy Group (MAPG). The MAPG will meet the first week of December 2008 to discuss the revised governance and business model, with the possibility of adoption by the MAPG. The document proposes to expand the number of trustees of the GMDN Agency from three to six.

R. Hammett stated that concerns remain regarding the document. Specific concerns mentioned include confusion over the roles of the different groups (i.e. trustees and the MAPG), an indication that the Agency would like to have a role in the policing of incidents of misuse of the nomenclature system, and a lack of change in the business model. The document also attempts to articulate a position on intellectual copyright that may not be supported by law

A discussion regarding the Asian Harmonization Working Party (AHWP) response to the governance document took place, and it was mentioned that while a formal response from the AHWP has not yet been received, R. Hammett expects to discuss the issue at the November 2008 AHWP meeting.

It was stressed that both Regulators and Industry want a single harmonized nomenclature system, and the GHTF SC will have to consider the decisions made at AHWP's meeting in November 2008 and adjust its position if necessary.

It was also mentioned that a funding offer made to the GMDN Agency, in which funding by the TGA and FDA for 2009 would be provided as the GMDN Agency transitioned to the new governance and business model, was rejected, and is unlikely to be re-considered by the Agency.

Action Items:

- Secretariat to circulate copy of GHTF response to WHO regarding the need for a single nomenclature system.
- L. Kessler to confirm with M. Freeman that the revised GMDN governance document can be circulated to GHTF SC and recommend that it be distributed to AHWP for review as well.
    - L. Kessler to forward revised document to Secretariat for distribution to GHTF SC.
    - Comments on revised document are requested to the GMDN AHWG (via R. Hammett) by end of day 17 October 2008.
    - On behalf of GHTF SC, R. Hammett to provide comments to the GMDN Agency by 31 October 2008; response requested from the Agency in advance of 11 December 2008 GHTF SC teleconference.
- R. Hammett to present on GMDN at the AHWP meeting in India on 5 November 2008, and inform GHTF SC of the AHWP's opinion on the revised governance document.

Training Partnership Update

L. Kessler stated that he is intending to organize a training partnership working group, consisting of subject matter experts from within GHTF. The intent is to organize a meeting, hosted by L. Kessler in Washington, for October or November 2008 to begin work on the training program curriculum.

It was noted that the GHTF Global Model document will be a very important tool to use when developing the training program.

T. Ulatowski suggested that the GHTF consider the CDRH Staff College as a possible resource to aid in the development of the curriculum, in partnership with RAPS and MTLI. A discussion surrounding this possibility took place, and questions were raised on how the GHTF could cooperate with training partners. L. Kessler will clarify what the details of this cooperative relationship would be.

It was decided that, as L. Kessler is leaving the FDA, R. Rotter will serve as coordinator for the training initiative.

Action Items:

- R. Rotter to serve as coordinator for the training initiative, and ask Study Group (SG) Chairs to nominate one participant to the working group per SG.
    - T. Ulatowski to participate in working group as representative from the Global Model AHWG.
- L. Kessler to confirm logistics of a meeting in late October/early November 2008 to develop training curriculum.
- L. Kessler to clarify details of cooperation with training partners (ie status update, processes for cooperation, etc)
- T. Ulatowski to follow-up on previous training sessions that were taped using FDA facilities, specifically regarding who was responsible for coordinating the taping, the current status of the DVDs, and the intended audience of the training.

Guidance on Management of Design and Process Changes

A discussion regarding the potential need for a guidance document on the management of design and process changes occurred. It was decided that there is no consolidated approach to how changes are assessed by the regulatory jurisdictions.

The possibility of SG1 taking this on as a work item was discussed, however, it was noted that SG1 currently has a busy work plan. This item will be discussed at the upcoming SG meetings in Ottawa. A preliminary scoping document may need to be drafted.

Action Items:

- Study Groups 1, 3, 4 to brainstorm this as a discussion item at the upcoming joint meeting and send feedback to J. Brinch.
- J. Brinch to send background information on the issue to SG Chairs as necessary.
- Following the brainstorming session at the SG 1,3,4 meeting, a scoping document may need to be drafted. Volunteers to draft this scoping document are J. Brinch, C. Wallroth and H. Ishikawa.

Study Group Updates

J. Garcia presented an update on the work of SG2. He noted that SG2 document N108R1 (Definition and Classification of Product Safety Corrective Actions, including Recalls) is anticipated for forwarding to the SC by the May 2009 meeting. SG2 and SG5 are collaborating on Adverse Event Reporting in the clinical trial phase. The XML pilot program has been delayed due to technical and logistical difficulties.

In response to a question, J. Garcia stated that SG2 reviews its documents on an ongoing basis (every three years), and updates on the implementation of its guidance documents at each SG2 meeting. Additionally, before each meeting, SG2 members are asked to review certain SG2 guidance documents to determine whether revision is needed.

Action Items:

- The possibility of reviewing the implementation of GHTF guidance documents at the SC level was discussed, but no specific action item at this time.-

G. Michaud presented an update on the work of SG1, beginning with an overview of the SG1 workplan. She noted that SG1 has several work items underway, and is also exploring the possibility of collaborating with SG3 and SG4 on two potential work items. SG1 will be discussing the combination products issue at their meeting in Ottawa next week, and it was stated that there is a need for clear harmonized definitions for combination products before the SG1 guidance documents can be revisited. She also mentioned that SG1 has expanded its membership to include two AHWP delegates, and an invitation to join SG1 has been extended to regulators and industry from Latin America and the Caribbean. At the July 2008 SG1 meeting in Buenos Aires, regulator representatives from Brazil, Panama, Cuba and Argentina, as well as industry representatives from international device firms were in attendance, and G. Michaud stated that they showed interest in the work of the GHTF, the GHTF model, and the program of major GHTF economies.

Action Items:

- None.

E. Cobbold presented an update on the work of SG3. He stated that membership has largely remained steady, but an invitation to participate in SG3 has been extended to a member of the

AHWP. The SG3 document N17 (Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers), will be finalized at next week's SG3 meeting in Ottawa, and will be put forward for approval by the SC following this meeting. SG3 also has two draft guidance documents in development (N18 and N19), and will continue work on these items. E. Cobbold added that the work plan of SG3 is quite full, and there are some concerns with requests that have been made for SG3 to undertake new work items. He added that the potential merger of SG3 and SG4 is also a concern for SG3 members, as it remains an unresolved issue. In response to a question regarding the frequency of SG3 meetings, E. Cobbold replied that he will try to minimize the expense to organizations, but face-to-face meetings are necessary to move work items forward.

Action Items:

- E. Cobbold to forward SG3 N17 for approval by the SC as a final document following the SG3 meeting next week.

G. LeBlanc (on behalf of the SG5 Chair) presented an update on the work of SG5. The SG5 document N4 (Post-Market Clinical Follow-Up Studies) has been distributed to SC members for approval to be posted as a proposed document on the GHTF website, and a decision will be made on this at the 11 December 2008 teleconference. The comment period for the SG5 document N3 has just closed, and the document will be discussed at the next SG5 meeting. G. LeBlanc indicated that work is ongoing to wrap operations of SG5 and transition into maintenance mode, and the initial plan for maintenance mode is to have one teleconference per year, however he stated that SG5 will welcome suggestions on the maintenance mode model. He anticipated that SG5 will need to meet a minimum of one more time face-to-face, but two to three face-to-face meetings may be necessary to wrap-up ongoing work.

Action Items:

- SG5 N4 will be brought forward for approval to post as a proposed document on the GHTF website at the 11 December 2008 teleconference.

T. Missios presented an update on the work of SG4. The SG will be meeting in Ottawa next week, and will be discussing the recommendations of the AWHG on Combination Products. SG5 has met face-to-face once since the Kuala Lumpur meeting in March 2008, a meeting in which N28 (Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements) was finalized. Additional items discussed by T. Missios were that the members of SG4 are keen to have a final decision made on the potential merger of SG3 and SG4, and a decision on the new Chair of SG4.

In response to a question regarding the possible CASCO liaison relationship that was discussed at the Kuala Lumpur SC meeting, T. Missios stated that no decision has been made on the item.

After waiving the normal 8-week time period to consider documents before approval, the SC members approved N28 for posting on the GHTF website as a final document. The European delegation provided the following statement:

The EU supports the endorsement of N28 of SG4 as a final document. However, it should also be pointed out that on some issues – such as the frequency of surveillance audits – compromises were made in the document. This means that the document would not as such be able to be applied in Europe, but specific requirements need to be taken into account.

On a more general note there is some concern that the GHTF global system reflects the approach based on a quality system and governmental approval only, but is also continuous to reflect the third party assessment as used in Europe. The GHTF model should allow countries that build up the systems, such as Asian countries, to follow either of the approaches."

Action Items:

- SG4 document N28 to be posted on GHTF website by the Secretariat.

Global Model AHWG Update

T. Ulatowski presented an update on the work of the Global Model AHWG and the status of the Global Model document. He indicated that he was looking forward to receiving additional comments on the document. The document is built upon current language used in existing GHTF documents, and contains information on the evolution of the GHTF model.

There was a discussion surrounding the use and adoption of the model by developing regulatory bodies.

Action Items:

- Global Model AHWG members and SG Chairs to send comments on the Global Model document to T. Ulatowski by 31 December 2008.
- T. Ulatowski to distribute updated Global Model document to SC members.
    a. Updated document to be discussed during February 2009 teleconference, and brought forward for approval at May 2009 meeting in Toronto.
    b. Document to be presented at May 2009 GHTF conference.

Software AHWG Update

S. Miura presented an update on the progress of the Software AHWG, which included the distribution of a memorandum with recommendations to the SC prepared by Brian Fitzgerald, Chair of the AHWG. A preliminary discussion on the recommendations took place, with members requesting additional time to review the document. There was also some discussion on the definition of terms related to software, and whether SG1 or the Software AHWG would be best placed to draft these definitions. Further discussion of this item is needed.

Action Items:

- Secretariat to circulate B. Fitzgerald's email and recommendations to SC members and Chairs of SG 1, 3, 4 with a request for feedback.
- To be discussed at 11 December 2008 teleconference.

HTAi AHWG Update

R. Rotter stated that the SC members had directed the AHWG to not move forward on establishing a permanent relationship with HTAi. R. Rotter met with the current president of the organization to gain a better understanding of the goals of GHTF and HTAi on the health technology issue.

Action Items

- None.

Regulated Product Submission and HL7

L. Boulay (Health Canada) presented information on the Regulatory Product Submission 2 (RPS2) and HL7 project. HL7 is a standards development organization intended to create standards for the exchange, management and integration of electronic healthcare information, while RPS2 is a HL7 standard to facilitate the processing and review of regulated product information. RPS 1 already exists. L. Boulay indicated that work is underway on the development of RPS2, and an aggressive timetable is in place. The working group consists of volunteers, and he suggested that a medical devices representative on the working group would be appropriate. An industry representative would also be welcomed.

Following L. Boulay's presentation, a discussion regarding the role the GHTF may play in this project was discussed, as the RPS2 will be a standard that will cover all regulated products, including medical devices. R. Rotter stated that, as Chair, he felt that a role for the GHTF should come after the development of the standard, and can be discussed at that time. M. Limoli added that she and Marianne Stack (FDA) could keep the SC informed of work being done by standards development groups on topics with implications for medical devices.

Action Items:

- M. Stack (FDA) and/or M. Limoli to update GHTF SC on topics with implications for medical devices, specifically related to the work of standards development groups.

Combination Products AHWG Update

M. Gropp presented an update on the work of the Combination Products AHWG. He stated that he had corresponded with the SG Chairs, and the most consistent comments related to the need to define terms (especially "combination product" and "medical device that incorporates a medicinal substance and/or materials of biological origin") consistently, to allow the study groups to do a more detailed review. The SG Chairs have added this topic to the agendas of their respective upcoming meetings, and the SGs have been asked to provide more detailed comments in response to the questions posed by the AHWG.

M. Gropp added that the AHWG has been in existence for approximately one-year, and as such is nearing the end of its 18-month mandate. As work is still ongoing, he suggested that the mandate may need to be extended, amended, or have the work draw to a close. This will be further discussed by the SC.

R. Rotter thanked M. Gropp for his work as Acting Chair of the AHWG, and the SC agreed that L. Kelly will assume the Chair of the AHWG.

Action Items:

- SG Chairs to review with their respective SGs the questions raised by the AHWG and report back to the AHWG and SC.
- Mandate of the AHWG to be discussed at 11 December 2008 or 26 February 2009 teleconference.
- L. Kelly to take over as Chair of AHWG.

Regulatory Approaches to Phthalates

J. Garcia presented information on the draft document which outlines the current regulatory approaches to phthalates in medical devices among GHTF Founding Members. He noted that, from the information he had received, there appeared to be six general points of agreement among the regulatory bodies on the approach to devices containing phthalates. A discussion regarding whether the GHTF should produce a position paper on the issue was held, and it was decided that at this time, the approach to regulating devices containing phthalates varies, and drafting one position paper will not be feasible.

R. Hammett and L. Kelly stated that the TGA will be drafting a position paper on the Australian approach to DEHP within the next six months, and will circulate this paper to SC members.

Action Items:

- TGA to circulate their position paper on the proposed Australian approach to DEHP to SC members.

Liaison Body Updates

T. Hancox provided an overview and update of the work of the International Organization for Standardization (ISO). A general introduction to the work and structure of ISO was presented, including the governance of ISO, the extent of the ISO system, and ISO's goal of achieving global relevance when developing standards.

In response to a question, T. Hancox stated that an MOU to cover all ISO technical committees had not been considered, but could be explored if there is an interest. There are MOUs between ICH and ISO, and ICH sends representatives to ISO meetings. M. Limoli was asked to bring forward information to the SC regarding these MOUs.

Action Items

- M. Limoli to distribute information on ICH-ISO MOUs to SC members.
- T. Hancox to forward current rules for the operation of joint working groups

C. Sidebottom presented an update on the International Electrotechnical Commission (IEC) and its Technical Committee 62 (TC 62), the TC responsible for most medical equipment. He highlighted some areas of potential interest to GHTF SC members, including the policy on dated references (use dated references when referring to other publications); normative references (language addition to this section); and the transition period (3-5 years).

In response to a question regarding representation on technical committees, C. Sidebottom stated that members are responsible for bringing subject matter experts into the process through participation in the meetings and by reviewing the standards; and a conscious effort is made by the committees to reach out to the user community, generally through workshops.

Action Items

- None

C. Wallroth presented the 4th GHTF rapporteur report to GHTF on medical device standards developments. The SC members reviewed the proposals contained in the paper, and made decisions on the pending issues.

Action Items:

- There was agreement to drop the Delta List issue due to lack of uniformity.
- C. Wallroth to report at the May 2009 SC meeting on continual product improvement.
- C. Wallroth to ask ISO for a status update on the latest draft of JWG IEC operating procedures.
- For CENELEC/TC 62, the GHTF SC agreed to recognize the good progress made, but a decision on the proposal to ensure alignment with the GHTF ad hoc group on software will be postponed.

Unique Device Identifiers

M. Neumann presented on the UDI issue, and proposed that the GHTF should create an AHWG on UDI. As the FDA is moving forward quickly with implementing UDI regulations, the AHWG will have an aggressive timetable, and will work to provide comments to the FDA before regulations are in place.

J. Crowley (FDA) presented an update on the FDA Amendments Act of 2007, which created the legal authority for the creation of regulations establishing a unique device identification system for medical devices and requiring the label of devices to bear a unique identifier. He indicated that he is open to suggestions on ways to ensure the UDI system is harmonized globally, and is looking to the GHTF for input.

Further discussion regarding the need for an AHWG on UDI took place, and SC members agreed to support the establishment of the AHWG.

Action Items:

- An AHWG, mandated with developing a scoping document on UDI, will be established with M. Neumann, C. Tarrajat and H. Ishikawa volunteering. Other volunteers welcome. TOR to be drafted including information what expertise the AHWG will require by 23 October 2008.
- Secretariat to send request for additional members in the AHWG, based on the expertise needed.
- Scoping document to be drafted in advance of 11 December 2008 teleconference.

Counterfeit Medical Devices/Products

T. Ulatwoski gave an overview of work being done by the FDA on counterfeit medical devices. He stated that there is some uncertainty surrounding the extent of the problem of counterfeit medical devices, but the problem is potentially growing. Examples of the medical devices that tend to be counterfeited most extensively are contact lenses, IVD products (glucose test strips), surgical mesh and condoms. He added that the manufacturers are being proactive in identifying instances of counterfeit medical devices.

M. Limoli stated that the WHO has a taskforce, IMPACT (International Medical Products Anti-Counterfeiting Taskforce), which is mainly focused on halting the production and sale of counterfeit medicines. However, the IMPACT working group which is responsible for developing a document for countries to use in drafting their counterfeiting legislation, has decided to include medical devices in their model legislative document, and will revise the document at a meeting being held on 25-26 November 2008.

Action Items:

- M. Limoli to bring draft legislative document developed by IMPACT for comment from SC members at May 2009 SC meeting in Toronto.

Glossary of Terms Document

H. Ishikawa updated the SC members on the status of the Glossary of Terms document. He stated that the document is being maintained, but mechanisms to continue maintaining it are needed. He asked that SG Chairs review the document to ensure the terms contained in it are consistent with their published and new documents.

Action Items:

- Secretariat to explore potential process for maintaining the Glossary.
- SG Chairs to review document to ensure terms are consistent with their published/new documents.

Upcoming GHTF Meetings (GHTF Conference)

R. Rotter updated the SC members on the planning underway for the May 2009 SC meeting and GHTF Conference. The SC meeting will run from Sunday, May 10th to noon on Tuesday, May 12th. The Conference will then begin in the afternoon of Tuesday, May 12th and will run to Thursday, May 14th. Training by GHTF members, sponsored by APEC, will run on Friday, May 15th and Saturday, May 16th.

The SC meeting and GHTF Conference will be held at the Westin Harbour Castle in Toronto, Ontario, Canada. A rate of $189.00 (CDN) has been secured for hotel rooms.

The GHTF training will take place at a different location (to be confirmed).

Ways to publicize the conference were discussed, and it was suggested that RAPS and DIA may be able to distribute information on the conference.

Action Items:

- Secretariat to distribute logistical information regarding SC meeting and GHTF Conference scheduled for 10-15 May 2009.
- Possibility of having RAPS and/or DIA distribute information on the conference should be explored by organizing committee.