SUMMARY OF THE 10th GHTF STEERING COMMITTEE

The 10th GHTF Steering Committee (SC) meeting was held in Lübeck, Germany from June 26 to 27, 2006.

1. Welcome and apologies

The Chair welcomed everyone to Lübeck.

Mrs. Georgette Lalis (EU) chaired the meeting. She welcomed the participants and invited them to present themselves.

Participating were, from Europe, Sabine Lecrenier, Jean-Claude Ghislain, Jos Kraus, Matthias Neumann, Wolfgang Ecker (observer), Maurice Wagner, Werner Schoenbuehler, Carl F. Wallroth and Christine Tarrajat; for Australia, Rita Maclachlan, Rohan Hammett, Brian Vale and Johan Brinch; for the US Larry Kessler, David P. Kelly, Daniel Schultz (observer), Janet E. Trunzo, Robert Britain, Michael Gropp; for Japan, Toshiyoshi Tominaga, Shinichi Takae, Shigetaka Miura and Hiroshi Ishikawa; for Canada, Roland Rotter, Omer Boudreau (observer); and the Study Groups Chairs, Ginette Michaud, Jorge Garcia, Alain Prat, Horst Frankenberger and Greg Le Blanc (Vice Chair SG5) as well as for the Secretariat Jean Olson and John Brennan.

Mr. Jeffrey Gren (US Department of Commerce) and Mr. Maurice Freeman (GMDN) attended portions of the meeting.

2. Approval of the agenda

The agenda was accepted unchanged.

3. Update GHTF Steering Committee Membership List and Contact Details

A listing, printed from the web-site was circulated. Steering Committee members were asked to update the list either directly to the Secretariat now or in the future by e-mail.

4. Summary Records from the 9th Steering Committee Meeting

The minutes from London were formally agreed.

5. GHTF Strategic Directions (mid-term review)

A report from the *ad hoc* group set up at the last Steering Committee meeting was presented by Mr. Gropp. The overall conclusions of the presentation were that:

- Strategic Direction document is essentially correct and appropriate
- Strategic Direction would benefit from more focus
- Goal 1 (emerging regulatory challenges) is least well understood or acted upon
- GHTF should encourage more focus on implementation and communication to interested parties
- GHTF needs more discussion on work areas and methods
- GHTF should consider broadening liaisons with other interested parties

The Chair congratulated Mr. Gropp on the excellent presentation and the obvious hard work and effort. A discussion on strategic direction followed, the conclusion being that we need to be very clearly focused and review the current strategy to allow the best possible basis to set the future 'Strategic Direction' for 2008 onwards.

The Chair asked that written comments to Mr Gropp's presentation and the strategic direction be submitted by mid-September and that this agenda item be given priority at the next meeting.

6. Study Group's work - Progress reports and documents

6.1. Study Group 1

Work Plan

The Chair of SG1, Dr. Michaud, presented the group's current work plan. Emphasis was made on the conclusion of the revisions of documents to incorporate *in vitro* diagnostic devices. A new work item on definition of "manufacturer" will be proposed in November.

In relation to the role of standards document, the Steering Committee noted that the question of transition needs to be dealt with clearly, as does noting that reference to standards is informative rather than normative.

Japan also noted that as they had several hundred STED submissions so they could provide real experience and valuable input to SG1.

Final documents

GHTF-SG1-N15-2006 Classification

This document outlines a rules-based (16 rules) medical device classification system. It divides devices into four classes, A, B, C and D. At present it excludes *in vitro* diagnostic medical devices.

One point of note in the document was the issue of diagnostic X-ray imaging devices. JFMDA see that they should be class B not C. The Study Group agreed to disagree and move the document forward with the issue being 'bookmarked' for future analysis.

Following the discussion on this point by the Steering Committee, the Chair suggested that the Study Group look at the example given on page 18 of the document in relation to these devices. The document was returned to the Study Group and resubmitted later in the Steering Committee with a slight amendment. This document was adopted as final by the Committee.

GHTF-SG1-N40-2006 Conformity Assessment

Overall there was good consensus within the study group for this document with one significant area of debate, Type Examination and its role in conformity assessment. The conclusion in this respect being that Type Examination must reside within the quality management system, it is always voluntary (can not be imposed by a regulator) and can only be allowed in a region that provides additional regulatory controls on design.

Dr.. Michaud thanked her group for their hard work, the previous Chair and the current Vice Chair, Benny Ons, and the Secretary, Alan Kent, and the IVD Subgroup Chair, Nancy Shadeed.

The Chair thanked Mrs. Michaud for the excellent documents and the document was adopted as final.

6.2. Study Group 2

Work Plan

The Study Group Chair, Mr. Garcia, presented the "Map" of SG2 Guidance.

Final documents

GHTF SG2 N79R7 National Competent Authority Report Exchange Criteria and Report Form

GHTF SG2 N57R7 Content of Field Safety Notices

The report form was presented and also the field safety notices document. On this latter document the Steering Committee asked that the Study Group reconsider its reference to the use of Risk Management. As it is currently referenced in the document it would seem that risk management according to ISO 14971 is the only or mandated method of assessing the need for a field safety corrective action.

This document was returned to the Study Group in order to look at this point. The document was subsequently re-tabled later in the meeting with wording to clearly indicate that use of ISO 14971 is only one suggested way of assessing risk and the need for field safety corrective action.

Both documents, N79 and N57, where then adopted as final.

Proposed Document

GHTF SG2 (PD) N87R7 guidance document bundle.ZIP

This proposed document is slightly unusual in that it comprises multiple parts that relate to electronic adverse event reporting by manufacturers to National Competent Authorities. Because of this the separate parts have been packaged into a single "ZIP" file bundle. The bundle contains the (cover) guidance document, an Excel spreadsheet which describes the code in detail and several files containing the code itself which can then be used in conjunction with software such as word processors and databases to "code" and "decode" the information contained in electronic reports compiled in accordance with SG2 N87R7 PD.

The Steering Committee discussed the documents along the lines of:

- Competence – Does SG2 have the necessary competence to develop such a document? Could it be part of a separate IT study group?
- Clarity – Is the document sufficiently clear to the 'uninitiated' reader accessing the GHTF web-site? Will a regulator from an emerging nation, looking to develop regulations, understand what this technical document is trying to achieve?
- Procedure – What the study group wants to do here is trial the 'xml' software format for data interchange. If it is not successful they may have to go back to the drawing board. Under the current rules of procedure this can only be done by making this a proposed document.

The conclusion was that as this document is primarily about vigilance and not software, the group should handle this issue. To address the clarity and procedure issue the document was adopted as a proposed document with a clear indication being given on the web-site that this is a pilot project and is subject to change. The Chair also noted that unusually this document will have a one year comment period and therefore asked Mr. Garcia to report on progress at the November meeting.

Hong Kong

This item was taken on the second day. It was generally agreed that Hong Kong and China would be welcome as NCAR program participants, and generally fulfil the agreed criteria. However, the Chair asked for more information on the link between Hong Kong and other Competent Authorities in China e.g. obligation for dissemination of information etc. The Chair offered to discuss this with SFDA at the opportunity of the upcoming EU – China meeting on 10, 11, 12 July 2006. Also each region will take up their appropriate contacts on the same issue. The application will therefore be re-discussed at November's meeting.

6.3. Study Group 3

Work Plan (election of new Study Group Chair)

The Chair of SG 3, Mr. Prat, presented the current status of work. He also announced that he will have to, reluctantly, step down as chair after the conference as he has taken a new position,..

The Chair thanked Mr. Prat for his work with the group and noted with regret his enforced departure. The Chair called for nominations for the upcoming vacancy. Mr. Egan Cobbold, Health Canada and current SG3 member, was proposed by Canada and seconded by Australia. This nomination was unanimously accepted by the Committee.

6.4. Study Group 4

Work Plan

The Study Group Chair, Dr. Frankenberger, presented SG4's current work plan.

Final documents

GHTF-SG4-N 30R19 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

This document was previously presented as a final document but sent back to the Study Group by the Steering Committee to look at incorporation of risk management (in association with SG 3). Canada has suggested one slight amendment which was agreeable to the Study Group. With this work done, including the slight amendment, the document is now complete and the document was adopted as final.

Retirement of Dr. Horst Frankenberger - Election of new Chair

Dr. Frankenberger will retire after the meeting and thus a new Chair needed to be elected. The Chair was aware that the current Study Group Vice Chair, Markus Zobrist, Swissmedic, had the support of the Study Group. The Committee endorsed Mr. Zobrist and he was elected as new Chair to Study Group 4.

Dr. Horst Frankenberger

The Chair wished to mark the departure of Dr Frankenberger. Dr Frankenberger has been one of the stalwarts of GHTF and global medical device affairs. His wealth of knowledge and reason in this area has been a constant steady hand, guiding GHTF from the moment of its conception fourteen years ago. His departure as Study Group Chair is regrettable, but hopefully he can continue to contribute to the efforts of GHTF, particularly in terms of training and education.

6.5. Study Group 5

Work Plan

The Study Group Vice-Chair, Mr. Le Blanc, standing in for Dr. Graeme Harris, presented the work plan for the group which currently revolves around the two proposed documents. SG5 intends to consult with SG1's IVD Subgroup in producing future guidance to address IVDs.

Proposed Documents

SG5(PD)N1R7 Clinical Evidence – Key Definitions and Concepts

SG5(PD)N2R7 Clinical Evaluation

Both documents were welcomed by the Committee most notably as clinical investigations are increasingly global and therefore this type of work is of utmost importance. Both documents were adopted as proposed documents.

7. Future approach on software – status report

Dr. Kessler, leader of the ad hoc group asked to look at software, presented a new study group proposal. A comprehensive list of proposals was presented. After discussion by the group, it was agreed to form an *ad hoc* group that can meet primarily by e-mail, and made up of representatives of SG members (nominations to be sent to Mr. Kessler by the 1st August).

The first item for this group to develop is their work plan for possible endorsement at the next Steering Committee meeting in November.

8. Follow-up from initiatives at last Steering Committee meeting

8.1. List of standards

A listing of those standards that are designated/harmonized in the different regions for regulatory purposes was submitted by the three regions (Japan noted that they will have to forward an update). This list was approved by the Committee and will be placed on the web-site.

[Secretariat Note: It was mentioned that the full ISO list of medical device standards should be listed, however this list is only a listing of those standards that are designated/harmonized in the different regions for regulatory purposes]

8.2. Proposal for GHTF Wordbook and Glossary

To compile this glossary, it was decided that each Study Group Chair should nominate a member who can provide lists of terms and definitions to Mr. Ishikawa of the Steering Committee who will lead a coordinated effort to create the glossary. Mr. Ishikawa was asked by the Chair to report on progress in November in Brussels.

8.3. Reprocessing of single use devices and regulatory approach in different regions

An update was given by each of the five founding members on the reprocessing of "single use" devices.

Australia – Reprocessors must comply with the requirements, including labelling, of the Australian medical device regulation. All healthcare facilities that reprocess critical single-use must now comply. There is also a requirement for patient informed consent. The use of the designation "single use" must be supported by evidence. Reprocessing of single use devices has diminished significantly.

Japan – There is no reprocessing of single use devices. This is illegal.

US – Essentially similar approach to Australia. In 2002, FDA was given legal authority to impose controls on reprocessing similar to those that that exist for new devices. For reprocessed "single use" devices, validation data would be needed. Regulation has limited the numbers of third party reprocessors (from about 20 – 30 to about 5 major reprocessors) and it has effectively stopped hospital reprocessing of single use devices. Approvals are publicised on the FDA web-site. The procedure has not allowed any device that presents a risk of transmission of CJD to be approved.

Canada – Health Canada had surveyed the market and situation in Canada and, as a result, had seen the need to regulate this area. However, in the recent weeks a legal jurisdiction issue has arisen questioning national and favouring provincial regulation.

EU – Arising from the current revision to the Medical Device Directives, and questions coming from the public consultation phase, the Commission is analysing this important area and the most appropriate rules to put in place. Similarly to Canada questions of jurisdiction arise, or 'subsidiarity' as it is known in Europe – should reprocessing be legislated at the national or EU level? Also, as reprocessing seems to happen without the device being 'placed on the market', and could be considered a 'service', an appropriate legal framework needs to be chosen.

8.4. Proposed Memorandum of Understanding between IEC and GHTF – follow-up

The Secretariat updated the Steering Committee on the desire of IEC, through IEC TC62, to become a Liaison Body to GHTF. This was welcomed by the group. The Chair asked the Secretariat to invite IEC to make a formal application.

8.5. Results of Health Care Technology Task Force (HTTF)

Mr. Neumann gave an update of HTTF through his involvement with their recent activities. Their goals are strengthening communication and optimal use of systems. There is an open question on how GHTF can best give input. The HTTF suggests that there should be a website that contains information on all medical device related standards and that GHTF should link to/endorse this. There should also be better participation of governmental experts. This raises some questions for GHTF. How can we give a real input to standardisation? Is it needed? If so how do we do it? Do we have a procedure? The Chair thanked Mr. Neumann and asked him to keep the Committee updated on activities with a goal to answering these questions.

8.6 GHTF Training

Mr. Gren (US Dept. of Commerce) gave a presentation on APEC funded training and the problems of securing GHTF regulators for training. This is a perennial problem and a number of open questions were raised: Perhaps we could contract a training group? Could we not use ex-members of Study Groups? Can we not train the trainers (e.g. AHWP)? Should we have a plan? Can we use this conference to assess demand?

The Chair concluded that the secretariat will gather currently available GHTF training information. Also based on the questions raised, each regulatory and industry founding member should contribute to Mr. Gropp's group looking at our strategy on training. Thus a strategy for the future can be developed

It was also reemphasised that all requests for GHTF training should go through the Chair for approval and sharing with all GHTF founding Members.

9. Status of Global Medical Device Nomenclature

Mr. Freeman gave a presentation of the GMDN Maintenance agency. There are now over 10,000 terms with 3 to 4 new additions per week. There are 15 main categories including non medical hospital purchasing items. GMDN is either being used, or foreseen to be used, in Europe, Australia, Japan, USA, Canada and in many Asian and South American countries.

Australia noted that they have 3 years experience and are working with teething problems. They encourage a hierarchical structure for in vitro diagnostic medical devices and are working, along with EDMA, with the maintenance agency on this. Also it was emphasised that redundant codes need to be retained somehow.

10. Discussion on potential last minute issues concerning GHTF Conference

Timing issues were discussed due to the unfortunate cancellation of some speakers.

11. Preparation of Open Session

A general review of the items for the open session took place.

After the open session Liaison Membership of ISO was discussed with unanimous acceptance of ISO as a Liaison Body.

12. Upcoming meetings

The next (and last European for this rotation) GHTF Steering Committee meeting will take place on 28th, 29th and 30th November 2006 in Brussels, Belgium.

Programme of North-American Chair

- 7 – 11 May 2007 Steering Committee and Joint Study Group Meeting in Los Angeles, California
- September 2007 Steering Committee and Plenary Meeting in Washington, DC
- February 2008 Steering Committee and Regional Meeting in Central/South America
- June 2008 Steering Committee Meeting, if necessary
- July/August 2008 Transfer Chair from US to Canada
- October 2008 Steering Committee and possible Joint Study Group Meetings, Ottawa, Canada
- February 2009 Steering Committee and possible Joint Study Group Meetings, Victoria Canada
- June 2009 Steering Committee and Plenary in Canada
- November 2009 Steering Committee and Regional Meeting in Central/South America
- February 2010 Transfer Chair to Australia/Japan

Open Session

Mr. Bjorn Falghren (World Health Organization), Dr. Pillay (Asian Harmonization Working Party and Mr. McKinley (ISO) joined the Steering Committee

13. Update of Main Developments in Founding Members Regulatory Systems

Japan: Gave a brief overview of the GHTF guidance that had been incorporated into the Japanese regulatory scheme along with an overview of this regulatory scheme. Japan briefly explained the steps, status as recognized manufacturers and approval of the application by MHLW, that make up the foreign manufacturers application process. Japan also briefly outlined the countermeasures it has taken to address the lag in device approvals in Japan. These include clinical trial consults, increasing the number of reviewers at PMDA, encouraging global development, approval of well established off label use, and acceptance of foreign clinical data (bridging studies are not mandatory).

Japan explained that approval of well established off label use can be asked for by patient associations, doctors associations, or industries and is typically supported by citing references in literature and information on definite use among advanced countries beyond Japan.

Australia: Australia reported on the progress made in the joint regulatory scheme for Australia and New Zealand. Under the scheme, both countries will be regulated by a joint agency, ANZTPA, a statutory agency that will be responsible to both the Australian and the New Zealand Parliaments and governments. ANZTPA is expected to be operating by October 2007.

ANZTPA will have offices in Canberra and in Wellington. ANZTPA will be governed by both the Australian and the New Zealand Health Ministers. The Ministers oversee a 5 member managing board. The board oversees the Managing Director of ANZTPA.

ANZTPA is responsible for regulating medical devices, medicines (prescription and non prescription), blood and blood components, and cell and tissue therapies.

Canada: Canada reported on its workload issues. They noted that great progress has been made to reduce the previous backlog on their application reviews for Class II, III and IV devices. Canada has tight review timeframes of, respectively, 15, 75 and 90 days for these device classes. Canada further noted that implementation of process improvements were moving to the next phase, the MDB Special Access Program. Canada signs off on 8,000 special access applications a year, primarily breast implants. That review would be followed by a review of the Investigation Testing (Clinical Trials) processes.

Canada also reported on its MoUs with TGA (mutual recognition of quality certificates), with Australia (quality systems), and with US (audits).

US: The US drew particular attention to its Medical Device Innovation Initiative. This initiative promotes early interaction between FDA and industry to optimize review times and foster innovation. Among the actions being taken by CDRH is the prioritization of guidance development that discuss regulatory requirements and review procedures to increase the consistency and transparency of its product review process. CDRH is also implementing a quality review program for premarket submissions to identify and apply best management practices internally.

The US also discussed FDA's regulation of combination products. In unclear cases, FDA's Office of Combination Products determines which Centre will have primary jurisdiction over the product. Products are then reviewed under the primary jurisdiction's Centre timeframes. The primary jurisdiction consults and collaborates with other Centres to assure an appropriate review. There is separate guidance on the application of quality system regulation to combination products.

Europe: As announced previously, this amendment of the Medical Device Directives does not change the framework or the approach of the Directives but rather introduces the necessary regulatory clarification in order to continue the high level of protection of human health and support better implementation.

The most significant areas where improvements are proposed concern conformity assessment, including design documentation and design review, clarification of the clinical evaluation requirements, Post Market Surveillance, compliance of custom-made device manufacturers and the alignment of Directive 90/385/EEC on active implantable medical devices.

The proposal also brings increased transparency to the general public in relation to the approval of devices. It foresees provisions to clarify definitions and demarcation with other regimes such as the borderline with the Advanced Therapy Medicinal Products

It is important to note that the proposal introduces a legal basis for cooperation between national authorities, including at international level.

14. Cooperation with international bodies (state of play)

14.1 WHO

Mr. Bjorn Falghren presented WHO's request that the public part of National Competent Authority Reports could be made available to WHO collaborate members. In many nations there are limited resources to operate a full regulatory system. Access to developed nations Vigilance information presents an opportunity to improve this situation. An active dissemination of information (recalls and restrictions of use) would be foreseen.

Concerns were expressed by the Steering Committee on previous experience with authorities who have not been trained in the NCAR programme and the meaning of the reports they receive, which has lead to inappropriate reaction to the NCAR.

It was agreed that an ad hoc group consisting of Mr. Ishikawa, Mr. Kraus, Mr. Kessler, Dr. Hammett, Mr. Gropp and Mrs. Trunzo should work with WHO on how to have the information that WHO wants on our web-site. It will be discussed in Brussels in November after the ad hoc group has done their work.

Also SG2 will need to augment the NCAR format to accommodate these types of requests. The Chair asked that SG2 submit this new work item proposal for the November meeting under 'Transparency'.

14.2 ISO

Mr. McKinley gave an update of ISO activities as part of consideration of its request to become a Liaison Body. It also emphasised the need for GHTF to comment on the development of a new Guide on the use of International Standards. The Chair asked the Secretariat to circulate the document for comment.

14.3 Asian Harmonization Working Party

A presentation was given by Dr Pillay, Chair of the Asian Harmonization Working Party, AHWP. It highlighted the activities of AHWP and in particular their close following and use of GHTF guidance, the need for support from GHTF to AHWP activities. In this regard, the GHTF Chair mentioned that GHTF is looking forward to shortly receiving and discussing the AHWP Liaison Body application. AHWP indicated that the application will be with the GHTF Secretariat in the very near future.

AOB

Application from other countries and regions, such as Cuba, can be expected in the future.