Summary 12th GHTF Steering Committee Meeting

The 12th GHTF Steering Committee (SC) meeting was held on 7-8 May 2007 in Irvine, California, USA. This meeting marked the beginning of the three year chairmanship of North America.

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1. Welcome

The meeting was chaired by Larry Kessler (US). The Chair welcomed all participants, who were as follows: from the US, Timothy Ulatowski, Gail Costello, David P. Kelly, Michael Gropp, Terrence Sweeney, Janet E. Trunzo (Vice-Chair); from Canada, Roland Rotter, Stephen Dibert; from Japan, Tomiko Tawaragi, Shinichi Takae, Shigetaka Miura and Hiroshi Ishikawa from Australia, Rohan Hammett, Anne Trimmer and Johan Brinch; from Europe, Laurent Selles, Jean-Claude Ghislain, Mathias Neumann, Jos Kraus, John Brennan (observer), Brian R Matthews, Christine Tarrajat, Werner Schönbühler, Carl F Wallroth,; from the Liaison bodies Mukundan.Pillay (AHWP); the Study Group Chairs Ginette Michaud, Egan Cobbold, Markus Zobrist and Greg LeBlanc (acting Chair SG 5); for the Secretariat Jean Olson.

2. Approval of the agenda

The Agenda was approved, with the recommendation that a discussion about Recalls be added.

3. Update GHTF Steering Committee Membership List and Contact Details

Steering Committee members agreed to recuse themselves from the discussion when a document came before the Steering Committee for consideration, if they had worked on that document as a member of the Study Group. The Steering Committee wanted to preserve the role of the Study Group Chair communicating to the Steering Committee about upcoming Study Group documents.

4. Summary Records from the 11th Steering Committee Meeting

The minutes had been approved earlier and have already been posted. No further changes or additions were requested at this time.

5. Steering Committee Initiatives

5.1. Training Ad Hoc

The Chair informed the Steering Committee that a first draft of the Training Report had been drafted and was being forwarded to the Training Ad Hoc working group for review. Action Item: The Training Ad Hoc working group intends to finish their report for the first teleconference, projected to be sometime in June 2007.

5.2. GHTF Website

The Chair began the discussion by noting that the Pan American Health Organization (PAHO) has translated several GHTF documents into Spanish and Portuguese. Dr. Pillay offered to have GHTF link to AHWP translations of GHTF documents. The Steering Committee discussed the following: 1) whether GHTF wanted to encourage translations; 2) whether GHTF wanted to change its policy of having official GHTF documents be in other languages in addition to English; 3) whether the responsibility for the translations lay with GHTF or the translator; 4) whether it was preferable to have the translations as part of the website or as links to the website with a notice that users were leaving the website when they clicked on the link; and 5) whether a translation tool, similar to the one used by GMDN to track the status of translations and to notify translators when new translations were needed would be something GHTF wanted to use. After discussion, the Steering Committee reached consensus that the official GHTF documents would remain the English language version posted by GHTF, it was important that there be a statement on the website that the English version is the official version, and that any translations would be the responsibility of the translator not GHTF. Action Item: Mr. Gropp and the Chair agreed to draft points to consider on the translation issues for the website for the next Steering Committee meeting. Steering Committee members are encouraged to share their thoughts on these issues with Mr. Gropp.

Members noted that some users may not have enough employees on site that were comfortable using English versions, and would find it helpful to have the documents translated. Members also noted that GHTF did not currently have the resources to translate GHTF documents to languages beyond English. Members further noted that a language may be spoken in more than one country, and that such multiplicity may complicate decisions concerning official translations.

Other discussions included whether it would be useful to have a specific section on the website that listed past attendees of GHTF meetings. A question arose about website usage. The Chair agreed to provide website

usage statistics to the Steering Committee. Other requests included having a link for high priority recalls on the website and having a section of the website restricted to Steering Committee members access to be used to post documents and information circulated in preparation for the Steering Committee meeting. A question was asked about the website search engine. Action Item: The Chair will forward the search engine name to the Steering Committee. It was noted that Google was an excellent search engine, albeit expensive.

Action Item: The Chair requested that the Steering Committee forward any comments it had on the mock-up of a new layout for the GHTF Website to the Chair or the Secretariat at the meeting of shortly thereafter.

The Chair asked for volunteers to work on the proposed GHTF website with the webmasters. The following volunteered or were volunteered: Paolo Catalani, John Brennan, Janet Trunzo, Terry Sweeney, Hiroshi Ishikawa, and Anne Trimmer. Dr. Rotter said he would forward the name of a volunteer. Note: Dr. Rotter later forwarded the name of Pauline Gaudry.

5.3. GHTF Workbook and Glossary

The Glossary is up on the website. The Chair thanked Mr. Ishikawa for his efforts. Mr. Ishikawa thanked the Study Groups for their contributions.

5.4. Retrospective Assessment

The Chair updated the Steering Committee on the progress of the Retrospective Assessment. He started by thanking everyone for sharing their insight. The Steering Committee had earlier agreed to conduct an objective assessment of its work and impacts over the past 15 years. The scope of the Assessment includes a forward-looking re-examination of the GHTF mission.

The Chair informed the Steering Committee that Beth Pieterson (Health Canada) has agreed to Chair the Retrospective Assessment. Others working on the Retrospective Assessment include Robert Britain, Horst Frankenberger, Elizabeth Krell (Jacobson), Alan Kent, Shigetaka Miura, and Brian Vale. Ms. Pieterson is considering adding a participant from Latin America and from the Asian Hamonization Working Party (AHWP) to provide a perspective from outside the founding members, but someone interested in GHTF. The Steering Committee supported the addition.

The Chair noted that the study approach has not been resolved, but that the Assessment would be relying on interviews to gather information. The Chair requested that Steering Committee members cooperate by making themselves available for interviews when contacted by the Assessment participants. The

target completion date is the end of the calendar year. The Chair informed the Steering Committee members that prior to it being made public, the Steering committee would be given an opportunity to comment on the report. Their comments would be attached as an appendix to the report. The Steering Committee supported this opportunity.

The Steering Committee discussed their interest in the Assessment providing forward looking recommendations, in addition to the retrospective assessment of work done. Action Item: It was recommended that the study plan be circulated to the Steering Committee. Dr. Pillay stated that AHWP was looking forward to receiving the Assessment. He noted that a similar study had been conducted in Asia.

5.5. Ad Hoc Working Groups

Mr. Neumann presented the proposal he and Mr. Gropp worked on regarding Ad Hoc Groups. It made recommendations regarding time limits, Chair selection, and scope of work. Generally the Steering Committee supported the proposal, however, minor changes were requested in the proposal to provide for greater flexibility. Action Item: Mr. Neumann and Mr. Gropp will revise and circulate the proposal at the next Telephone Conference. The Steering Committee intends to revise their operating procedures once agreement on the Ad Hoc working groups proposal is reached.

Under the rubric of Steering Committee commitment to Ad Hoc Working Group issues, the Steering Committee discussion touched on the following: 1) whether the Ad Hoc Chair should be a Steering Committee member; 2) whether to limit Ad Hoc Group members to GHTF participants, 3) whether every Ad Hoc Group should include a set number of regulators; 4) whether to include a recommendation that every Ad Hoc Group should be balanced regionally and/ or include at least 3 regulators; 5) whether Ad Hoc Group members selection should give greater importance, to expertise or regulator/industry balance; 6) whether some issues requiring extensive technical expertise would be better handled by standard setting organizations; 7) whether it would be advantageous to have vice chairs of Ad Hoc Groups; or 8) whether a set term limit for Ad Hoc Groups circumscribed the flexibility unnecessarily. It was decided that the Steering Committee should provide greater clarity regarding scope and mandates for Ad Hoc Groups at the time of the ad hoc group's creation.

5.6. Technology Assessment Organizations

Members were requested to bring information about Health Technology Assessment organizations and Health Technology Assessment International (HTAi) to the meeting. The Steering Committee exchanged views on possible

coordination with HTAi. Concerns were expressed about whether it was premature to consider coordinating with health technology assessment organization because reimbursement issues appear to be their current focus and whether health technology assessment was sufficiently harmonized for a dialogue to be meaningful. At the same time, as medical device regulation expands further into post market regulatory activities, the possibility of overlap with health technology assessment could grow. The Steering Committee reached consensus to explore the possibility of future coordination between the two organizations. Action Item: To begin a dialogue between the two organizations, the Chair intends to invite Reiner Banken of Health Technology Assessment International (HTAi) to the upcoming October 2007, Steering Committee meeting in Washington, DC, to share information about HTAi and its goals.

5.7. Awards Program

It was proposed that GHTF give consideration to presenting an annual award to an outstanding contributor. Among other criteria it was proposed to consider individuals in leadership positions whose service had significantly advanced the mission of GHTF. The Steering Committee exchanged views on the possibility of creating an Awards Program and decided it was premature to have such a program. Several members noted that it was not in their culture to have an Awards Program. Concerns were expressed about ability of the organization to recognize all of the individuals deserving recognition of their efforts, whether it would be better to recognize the service of all by having an award recognizing length of service, whether some other form of recognition would be more appropriate such as posting the recognition on the GHTF website, whether thanking individuals outside of GHTF participants would be more appropriate, and whether it would be more appropriate to thank involved individuals and organizations at the end of GHTF documents.

The Steering Committee concluded that having an Awards Program was not where they currently wanted to put their limited resources.

5.8. Implementation report

Mr. Ulatowski reported on the Implementation Report. Regulators from Australia, Canada, EU, Japan and US sent reports to Mr. Ulatowski, indicating their level of implementation of GHTF documents. Mr. Ulatowski compiled these individual reports into one report.

He noted that Australia seems to be implementing GHTF documents the more completely, followed by Japan, Canada and US. The EU adopts many documents in part. Overwhelmingly the documents are adopted in part. If comparing partial adoption of GHTF documents, Australia, EU and Japan are

on par. There is also the issue of what each Regulator meant by adoption in their individual reports.

Avenues of adoption take different forms. Statutes are not the only barriers to adoption. It was acknowledged that changing a statute was often beyond the power of a Regulator. Within existing statutes, Regulators are sometimes able to find other mechanisms for adoption. The Chair wanted to know if there was any document that no one could adopt; there are none. The Chair also wanted Regulators to communicate if there was something GHTF could do to help countries adopt a GHTF document.

The Chair thanked Mr. Ulatowski for an excellent report. A member noted that the report was a useful snap-shot of implementation. He recommended that it would be useful if the report was done annually. Members suggested that both regulator and industry information would be helpful in revising the information. Members suggested that more context may be needed such as adding references, definition of terms, links to the regulations, statutes or guidances where the GHTF documents had been implemented. A Member noted that it could be a powerful tool to debug the system. Members recommended that each member review the document and suggest revisions where it may be inaccurate. Action Item: The Chair agreed and asked members to send their revisions and comments to Mr. Ulatowski and Ms. Olson by 1 June 2007.

Another Member noted that it would be interesting to obtain the view of the Retrospective Assessment Group on this report. The Steering Committee agreed and said it would share the report after the revisions had been completed. Action Item: The Study Group Chairs were also asked to think through the obstacles faced on their documents and to note where documents or elements of documents have proven to be too difficult to harmonize and/or implement, and then consider whether such issues should be re-opened.

Mr. Sweeney proposed that the long term goals for implementation be well defined. He suggested that single document approvals and single audits were appropriate goals. He recommended that key performance indicators be created to measure progress. He suggested that a goal should be approved once and accepted everywhere. He noted that the past hard work of GHTF meant that the fundamentals were done, and that it was now time to move on toward recognizing each other's work. Dr. Pillay noted that ASEAN could be used as a model where work accepted in one country was accepted in 10 countries. The Chair noted that Regulators need to build confidence in materials submitted. The Chair urged Industry to support pilots and other opportunities that allow Regulators to build confidence. It is hard for Regulators to get to the next step without the confidence building step. The Steering Committee agreed that Regulators and Industry need to fact find

together about why participation is less than optimal in confidence building projects.

5.9. Combination Products

Ms. Olson reported on Combination Products. Ms. Olson took all of the individual Regulator reports and compiled them into a side-by-side comparison. She noted that all members are regulating combination products, even if they do not call them combination products.

In terms of defining combination products, Canada and the US define combination products. Australia and the EU regulate them as Class III medical devices with ancillary medicine components. Japan regulates them as a drug or device, according to the main purpose. Australia and Canada address combinations of drugs and devices. The EU, Japan and the US address combinations of drugs, devices and biologics.

Canada, the EU and Japan do not have unique procedures for determining the lead agency or authority in the review for combination products. Australia has established a Committee where combination products can be referred if the lead agency is unclear. The US has established an Office of Combination Products in the Commissioner's Office to refer combination products.

Canada has a created a process with duplicate data sets to assess where two products are intended to be used in conjunction with each other. Australia, Canada, the EU and the US have established procedures that specifically require non-primary component consultations for combination products. Separate applications for investigational combination products are not typically required by Regulators. No Regulator has a separate GMP/QS, registering and listing or adverse event reporting requirements for combination products.

Ms. Tawaragi presented an overview of Japanese regulation of combination products. Pharmaceuticals and medical devices are regulated under Japan's Pharmaceutical Affairs Law (PAL). Co-packaged or combined devices and drugs are considered combination products, but "cross-labelled" products are not recognized as combination products. A combination product is regulated according to its primary mode of action by MHLW's Pharmaceutical's Evaluation Division, Medical Devices Evaluation Office, or Compliance and Narcotics Division.

A single device or drug SHONIN application can serve for a combination product regulated as a device or a drug, or the applicant can submit two applications. Drug eluting stents are regulated as medical devices. Pre-filled syringes are regulated as drugs. An Iontophorsis system is regulated

as either a drug or a device depending on whether the reservoir can be refilled. If it can, it is regulated as a device.

Mr. Kraus presented the legal status of combination products in Europe. Medical devices, medical products, animal tissues non-viable, human tissues viable and human tissues non-viable are regulated (or perform conformity assessments in the case of Notified Bodies) by Notified Bodies or the European Medicines Agency (EMEA) or a Local Agency. There is a moratorium on using viable animal tissues.

Based on the side-by-side comparison and the presentations of Japan and the EU, Members expressed interested in the opportunity for prospective harmonization through a Study Group or an Ad Hoc Group and it was supported by the Steering Committee. Because the Steering Committee wanted to move quickly they decided to form an Ad hoc Group that would define combination products and that would recommend a course of action for a subgroup of Study Group 1 participants. Action Item: Mr. Brennan, Mr. Gropp, Mr. Matthews, Mr. Rohan, Mr. Takae, Ms. Trimmer, and Ms. Trunzo volunteered. Ms. Maclachlan will Chair the Ad Hoc Group. Once the scope is identified, GHTF should invite someone from ICH.

5.10. Software Ad Hoc Group

Brian Fitzgerald, Chair of the Software Ad Hoc Group presented the following 12 recommendations to the Steering Committee.

Recommendation #1) Related to activity 1 of the approved proposals

Action Item: Recommendation to Study Group 1; Please provide either a supplementary clause or a more inclusive text to Essential Principle 5.12 which will relate to standalone software since under the current text standalone software may not be covered because there is no "…energy source."

Rationale: The definition of "device" in many jurisdictions already contemplates standalone software, and while the system in which the standalone software is installed may have potential for energy transfer hazards the entirety of hazards arising from defective software are not limited to those mitigated by conformance to the sub clauses of 5.12.

The Steering Committee supported this recommendation.

Recommendation #2) Related to activity 1 of the approved proposals

Recommendation to Study Group 1: Please replace the language used in Essential Principle 5.12.1 with elements of the draft language to be used in the new MDD.

The current text reads:

> *5.12.1 Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.*

The recommended text should mirror, as far as possible, the text proposed in the forthcoming revised European medical directive:

> *5.12.1b For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.*

Rationale: The reference to "…repeatability, reliability and performance of these systems according to their intended use" has little practical use where software is concerned since even defective software is perfectly repeatable and reliable though it may not perform as intended. The proposed new language may be directly coupled to published consensus standards which represent the current acknowledged state of the art.

Note: Proposed amendment 22 (October 10, 2006) of the proposed MDD draft text now reads; *12.1a. For devices which incorporate software, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.*

The Steering Committee decided that will need to consider further to ensure that the recommendation is not detrimental to harmonization.

Recommendation #3) related to activity 1 of the approved proposals

Recommendation to Study Group 1: Please clarify the definition of "software" by defining several related terms (embedded, standalone, installable, programmable, configurable, system, accessory, firmware, off the shelf, etc.).

Rationale: The way in which the *Essential Principles* and other related guidance are applied may relate to the context of the software's environment, its use, its maintenance and provenance and therefore these definitions need to be settled.

Action Item: The Steering Committee asked the Software Ad Hoc Group develop the clarification and then pass off to Study Group 1.

Recommendation #4) related to activity 1 of the approved proposals

Action Item: Recommendation to Study Group 1: In the *STED* guidance clause 7.2.4 please include a reference to software referring to *Essential Principle* 5.9.1 and 5.9.2 which highlight the need for documentation and assessment relating to the possible negative interactions between software and other influences, hardware, EMC, language, etc. in its use environment .

Rationale: This has special significance for standalone software in that the manufacturer of such software may not be able to know the explicit properties of the particular hardware platform in which the software will eventually be installed. Therefore there should be, to the greatest extent possible, the provision of a detailed generic specification of the hardware platform 'envelope' which the software manufacturer has considered in the software design and links between this hardware performance envelope and the results of the manufacturers software verification activities.

The Steering Committee referred this recommendation to Study Group 1.

Recommendation #5) related to activity 1 of the approved proposals

Recommendation to Study Group 2; Please supplement the examples provided and clarify the requirements in various documents under the study group's control for which affected parties should undertake adverse event reporting, particularly with regard to networking scenarios. The Software Ad-hoc team can assist in this task if necessary.

Rationale: The devices may each be working as intended according to the manufacturer's specification but when linked together they may cause the hazardous situation (example; lack of timing synchronization, Bluetooth bit error rate failure, unmatched security controls, etc). The regulatory burden of reporting device failures should also fall on those who observe installed system failures to properly capture the root causes of individual device failures.

Action Item: The Steering Committee asked Mr. Ishikawa and Study Group 2 to take the lead on this recommendation.

Recommendation #6) related to all activities of the approved proposals

The Ad Hoc group recommends that it be converted into a task group and located under Study Group 3, at Study Group 3's request, so it may freely move between and assist other study groups and act as a resource, as needed. This task group would implement any current recommendation which may be accepted by the Steering Committee and Study Groups.

Rationale: These activities are cross-cutting through many technical domains and study groups and it is important to maintain consistency in approach and membership. An on-line working environment has been established in which the membership can communicate and share documents asynchronously when required. This private web-portal can increase the throughput of the Ad Hoc deliberations and provide speedier resolutions of issues, without having to rely on physical meetings. The software group feels that it should minimize the risk of being seen as another autonomous Study Group and by acting under the auspices of SG3 it should be provided sufficient structure while active.

The Steering Committee decided to maintain the Software Ad Hoc as an Ad Hoc Group and review the progress next year prior to making a decision to make it a Subgroup of a Study Group.

Recommendation #7 related to activity 1 and activity 10 of the approved proposals.

Action Item: Recommendation to Study Group 3: The Ad Hoc group recommends that SG3/N17R3 now begin to make reference to procurement of software and outsourcing of software.

Rationale: These functions are critical for the proper inclusion of product and process controls in outsourced software development and the use environment for both standalone software and software which is a component of a medical device.

The Steering Committee agreed to this recommendation.

Recommendation #8 related to activity 6

Action Item: Recommendation to Study Group 3: Please make reference to software controlled processes in SG3/N99-10 and remove the software exception currently in place. Make it clear that process validation applies to software design activities. Reference to software validation activities and the appropriate standards can be included.

Rationale: It is critical for proper manufacturing process validation, where software controlled processes are present, that the extent of software validation be defined and documented. Software Quality Assurance controls should exist both in device design and device manufacturing. The proposed text of the new European MDD now contemplates software validation, software verification and software lifecycle activities.

The Steering Committee agreed to this recommendation and asked Study Group 3 to undertake it.

Recommendation #9 related to activity 10

Action Item: Recommendation to Study Group 4: The Ad Hoc Group recommends that a software specific quality audit document be developed. The scope of the software audit process should be focused on both design side QMS aspects and product integrity.

Rationale: The current document cannot be easily "scaled" to software audits and the Industry Standard processes for Software Quality Assurance rely on a discrete subset of the elements covered by the current document, (e.g less reliance on verification). Published standards, specifically IEC 62304, now provide a basis for such an improved audit approach.

The Steering Committee decided this recommendation should be referred to Study Group 4 to deal with after their current work priorities.

Recommendation #10 related to activity 1

Recommendation to Study Group 5: The Ad Hoc Group recommends that the software which autonomously controls therapy delivery and/or autonomously performs diagnosis may, in certain circumstances, require clinical evidence as part of its validation.

Rationale: It may be relatively rare but when closed loop software is, or controls, a medical device it could require clinical evaluation to validate it.

Action Item: The Steering Committee asked the Software Ad Hoc Group to discuss this recommendation with Study Group 1 prior to the Steering Committee deciding on this recommendation because the Steering Committee needs more information.

Recommendation #11 related to all activities

Recommendation to all relevant study groups: Please provide consideration, clarification, definitions and guidance for medical software that is not a device but which, as an accessory to a device or its patient related data, may be regulated as a device.

Rationale: A class of medical software is emerging which may not meet the definition of a traditional device itself but which may be an accessory to a device, or may manage devices through clinical workflow management. This area may not be covered by every jurisdiction's medical device regulations but an increasing number of jurisdictions are placing controls on these activities.

Emerging standards in this area may complement GHTF activities undertaken here.

Action Item: The Steering Committee asked the Ad Hoc Group to refine the recommendation because the direction was unclear. They asked the Ad Hoc Group to highlight examples.

Recommendation #12 related to activity 1 and 10

A criteria based guidance should be developed to complement the new Software audit document (see recommendation 9).

The Ad Hoc Group asked the Steering Committee to direct SG3 and SG4 to jointly decide whether GHTF should develop a guidance for regulatory criteria for software audit, complementary to the requested Software quality audit document, or refer it to ISO/IEC for TC210 for a standards activity.

Rationale: This would be a complementary criteria document (checklist) to the process centric audit methodology in recommendation #9.

The Steering Committee noted that they would raise this recommendation with Study Groups 3 and 4 later in the day.

5.11.Action Plan - Not discussed due to time constraints

5.12.Training Slides – Discussion of Control issues

The Steering Committee reopened their on-going discussion of control issues for training slides. The Steering Committee values transparency and sharing their model with the public. However, some expressed concern that outside contractors sometimes take GHTF presentations and use them as their own, and sometimes imply that they are representing GHTF. Some indicated that the value of having GHTF products available outweighed the misuse of a few contractors.

Various methods of control were raised. One method discussed is copyrighting documents. Another method raised is sending cease and desist letters to people that misrepresent their relationship with GHTF. Another supported a proactive solution – such as informing organizers of major meetings that the organizers should come to GHTF for updates on GHTF or for training on GHTF documents. Some supported developing a script for GHTF presentations as a way to control the GHTF message, and ensure the correct information is presented. A member suggested GHTF ask for good faith cooperation with GHTF procedures. Another suggested that Power Point versions be left on a secure portion of the GHTF website.

No consensus was reached on the control method preferred. However, consensus was reached that GHTF presentations should be shared on the GHTF website, where such sharing was practical.

6. Update of Main Developments in Founding Members Regulatory Systems

Australia

Australia updated the Steering Committee on the transition process of regulating medical devices jointly with New Zealand. They are currently in Phase 3 of the transition. The Therapeutic Products and Medicines Bill, part of the implementing legislation, has been introduced to the New Zealand Parliament. Australia has released a draft of the Australian Therapeutic Products Bill for comment.

Australia is about to start a formal review of health technology assessment. They are looking toward incorporation of post market data from health outcomes registries.

On the subject of Study Group travel and meetings, Australia asks Study Group Chairs to consider other methods of communication, not just face-to-face meetings.

Japan

Japan updated the Steering Committee on the establishment of new Japanese Study Groups on software, nomenclature, especially the Japanese Medical Device Nomenclature (JMDN), and the status of pharmaceutical affairs.

Japan is beginning a study of the medical device "lag" issue. The medical device lag issues refers to where some high risk products (typically, but not limited to, higher class devices) are approved elsewhere, but have yet to be approved in Japan. Japan has created a task force to address introducing innovative devices into Japan.

Canada

Canada updated the Steering Committee with the information that Omer Boudreau has left the Therapeutic Products Directorate (TPD). Health Canada is looking for a new Director General of TPD. Canada noted that Health Canada has initiated a complete review of all product line programs in the Health Products and Foods Branch, including medical devices with a goal of achieving consistent resources and that the previous fiscal year reduction in review times. In addition, cost recovery fees for medical devices, pharmaceuticals, biologicals and natural health products are being reviewed. Consultations on the new fees will begin in June 2007.

Canada will be reviewing their Food and Drugs Act to determine how regulations regarding reuse of single-use devices could be developed. A Private Member's Bill in the Canadian Parliament which called for banning the use of phthalates in medical devices, cosmetics and consumer productswas not passed, but the bill was revised to require the Minister of Health to, among other things, regulate the labeling of medical

devices containing phthalates and encourage the phase-out of the use of phthaltes. Another Private Member's Bill in the Canadian Senate was introduced calling for the Minister of Health to establish and maintain a National Device Implant Registry. Health Canada is also revising its Clinical Trials regulations for medical devices.

Health Canada's MOU with FDA on Pilot Multi-purpose Audit Program (pMAP) is moving forward. Health Canada's MOU with TGA recognizing each other's QMS audits, is expected to be signed in June 2007.

United States

The US updated the Steering Committee by discussing a number of ongoing issues. The Pilot Multi-purpose Audit Program (pMAP) is moving forward. A link to a question and answer pmap posting can be found at this address http://www.fda.gov/cdrh/ap-inspection/pmap-qa.html. MDUFMA, the US medical device user fee act, is being renegotiated. The version of the bill in the US Senate, is the version negotiated between industry and FDA. There are two versions of bills to regulate "home brew" IVDs in the US Senate.

The FDA is engaged in a post market safety effort. It is aimed at establishing a faster exchange of information inside FDA. FDA hopes to have its electronic registration and listing effort in place by October 2007. Portions of the electronic mandatory device reporting have been implemented. CDRH's new tracking system for post market studies has improved tracking of clinical studies. Briefly updates on UDI, GMDN, off label promotion and status of STED submissions (25 to date) were discussed.

Europe

Europe updated the Steering Committee about the Revision of the European Medical Devices Directives (MDD). The Directives are currently being revised. The European Parliament negotiated 141 amendments, the European Council (EC) had more than 90 amendments. Nine of 12 annexes of the MDD are revised. The EC expects to issue further guidance on some issues.

Europe noted that some fine tuning of the current MDD is necessary with regard to clinical evaluation, conformity assessments, uniform application of rules for classification and demarcation, some reclassification issues, and principles of design for patient safety. Changes proposed by European Parliament include the following: definition of single use added, regulation on reprocessing (EC directed to propose), labelling requirements for single use devices (SUD) and for devices containing DEHP.

Clinical evaluation changes include clarification that clinical evaluation is necessary for every device, emphasis of Clinical evaluation as part of technical documentation, obligate notified bodies to assess technical documentation as part of their conformity assessments audits, and clarification of the principles of clinical evaluation. Further changes include implementing post-market clinical follow-up as part of

manufacturer's post-market studies activities and improving exchange of information regarding clinical investigations between competent authorities.

Conformity assessments changes include requiring design examination for the following: mid-risk devices on a representative basis, at least one representative product of a manufacturer's portfolio (done by notified body), at least one product per subcategory of class IIa product, and at least one product per generic device type of class IIb products. These changes are intended to provide evidence that approved and assessed Quality Management Systems produce safe and effective medical devices.

Some classification and reclassification issues were also addressed. The definition of medical device has been expanded to include stand-alone-software. This does not include software that has no medical purpose. Any surgically invasive device intended for use in direct contact with the central nervous system are Class III. Devices intended for recording x-ray diagnostic images are Class IIa. Devices intended to be specifically used to disinfect invasive devices have been reclassified into Class IIb.

Other changes have been added. They include requiring better consideration of ergonomic features as well as better consideration of mental, physical and health conditions of patients and users. Whilst still regulated under the MDD, to meet the essential requirements of the MDD, manufacturers of devices that are also machinery must look to the essential requirements of the Machinery Directive to identify any 'more specific' essential requirements, that must also be met . Software must be validated according to the state of art.

Additional labelling requirements have been added. Specific labelling requirements for Single Use Devices devices are proposed. If a manufacturer knows a device will be reused, the manufacturer is required to provide information on the known risks. And devices that contain phthalates must be labelled with a warning, if those devices administer, remove, store or are for transport of medicines, body fluids or other body substances.

A further change delineates a procedure for a Member State to request from the European Commission (EC) the status and product risk class decisions for a device. In the past MEDDEV guidelines are determinative, but they are not legally binding on all Member States. This procedure allows the EC to create a decision that could be legally binding across the EU.

The time periods for keeping device documentation available to national authorities have been modified. Manufacturers (or their authorized representative) must keep documentation for at least five years. And manufacturers (or their authorized representative) of implantable devices must keep documentation for at least fifteen years. The time periods were modified because the lifetime of a device cannot be defined.

Europe also described the revision of the New Approach, general legislation that applies across many industry sectors. The New Approach regulation is intended to make

it easier for a manufacturer to market their products in Europe and improve market surveillance. It provides for leaner regulation of the internal market in Europe. It establishes essential requirements for market approval of products. The essential requirements are typically specified by European or international standard bodies. There should be no or only very limited involvement of governmental authorities into accreditation of conformity assessment bodies.

Clarifying that he was speaking as a Member State representative, Mr. Neumann noted that some Member States are not in support of the aspect of the revised New Approach that allows member states to delegate supervision of Notified Bodies to private organizations.

The EC said it sees in the envisaged system of accreditation an empowering instrument designed to help the national authorities when they designate the Conformity Assessment Bodies (Notified Bodies). The envisaged new legislative act should reinforce the competence level of the Conformity Assessment Bodies and reduce the existing risk of divergence of interpretation.

As a response to the concern expressed in the so-called "Bonn Resolution," the EC said a detailed clarification has been forwarded to the European Member States. It is, by the way, the only aspect of applicability of the forthcoming new legislative act for the medical device sector, since medical devices are exempt from the requirements relating to market surveillance (as the present medical device regulation is more severe than the forthcoming revised New Approach).

Europe noted the *Guidelines on Medical Devices, IVD Guidances: Supply of Instructions for Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices* (MEDDEV) defining the circumstances under which the IFU for IVDs can be provided through means other than paper copy together with the product – via the Internet, for instance, has been endorsed by all Member States on 13 December 2006 during the plenary session of the MDEG (Medical Device Expert Group - formal EC group that endorses this type of document) and is now available on the EC website.

Europe further noted that following the presentation of a draft revision of the current Common Technical Specifications (CTS) for Annex II *in vitro* diagnostic devices during the plenary session of the MDEG on 13 December 2006, a comment period was open until the end of January 2007. The comments received have been carefully analysed and the new revision should be published soon.

AHWP asked whether the changes followed the GHTF model? Europe began by explaining the New Approach was much broader than medical devices. But in spirit the changes are within the GHTF model. Approximately 80% of the changes reflected the current GHTF model. Achieving consensusis a challenge when bringing 27 countries to the same point. They noted further that the follow-on documents, will clarify where harmonization has taken place.

Australia expressed concern that the New Approach may make it difficult for Australia to accept the evaluation of European notified bodies. If this is the direction Europe is heading, in allowing Member States to delegate the supervision of Notified Bodies to private organizations, this would have major implications for Australia's MRA with Europe and for European devices.

Canada supported Australia's expression of concern. Canada noted that in the recent past it has ceased to recognize two registrars because they were not fulfilling their required duties. When private organizations are doing the supervising, Canada is not as assured about motivation. Government officials should make this safety and effectiveness call.

The US supported Australia's concern. The US noted their intention to comment on the document.

Japan supported Australia's concern. Japan requested that the Europe slide presentation be sent to the Steering Committee soon.

The EC reiterated their support of the revised New Approach and noted that some participants have expressed concern vis-à-vis the forthcoming revision of the New Approach. The idea has been suggested that the revised New Approach might reduce the competence of the national authorities in the matter of the designation of the notified bodies. At the present stage of the adoption procedure of the legislative act, this idea is unfounded.

European Industry, like the European member states, includes supporters and non supporters of this aspect (that allows member states to delegate supervision of Notified Bodies to private organizations) of the revised New Approach. During the meeting EDMA expressed their support for the revised New Approach.

7. GMDN

The Chair presented the Global Medical Device Nomenclature (GMDN) business plan report. It was noted that the report was incomplete because the income information was missing. It was unclear if the annual income covered the costs of operation. Several members noted their concern about GMDN's lack of transparency, support and structure. Regulators and Industry are concerned with the future of GMDN as structured and want to take steps to make it sustainable because its work is excellent. Action Item: The Chair will contact GMDN for more information on its business report.

The possibility of having the US's National Institute of Health's (NIH) National Library of Medicine (NLM) adopting the maintenance of GMDN was raised. In addition to its expertise in database management, the advantage of having the NLM take on GMDN, is that it would be freely available internationally. It was noted that NLM does not do translations. Other countries would need to nominate a translator. It is expensive to translate, but it is less expensive to update.

Japan then presented their experience with JMDN. Japan translated the first group of GMDN terms, when it had approximately 4,046 terms. It is used to define regulatory classification of devices. Companies are required to use JMDN terms in their adverse event reporting. A JMDN Study Group has been formed to examine the best way to revise JMDN.

8. UDI

The Chair discussed Unique Device Identification (UDI) as it is used at the United States of America Food and Drug Administration. He noted that it was a combination of the following three distinct ideas: 1) development of a standardization system of unique device identifiers, 2) placement of UDI in human readable and AutoID on device, its labelling or both, and 3) creation of the UDI database containing a minimum data set. In August of 2006, FDA asked for comments on using UDI to improve patient safety. FDA continues its analysis of those comments. FDA believes UDI can reduce medical errors, improve device identification in adverse event reports, assist in more effective device recalls, provide device use information for electronic medical record systems, and provide other ancillary benefits.

Japan and Australia noted that they were also in the process of developing UDI systems. The EU noted that they had been working with GS1. Action Item: The Regulators agreed to forward information on developments in UDI for their Regions to the Chair.

9. Cooperation with international bodies

9.1. WHO & NCAR

Jorge Garcia noted that Study Group 2 had extended an invitation for the World Health Organization (WHO) to join the NCAR program as an associate participant. WHO declined, and suggested that they act as a facilitator and trainer for Ministries of Health outside of GHTF to join the NCAR program. He further noted that Study Group 2 accepted and agreed with the decision and the collaboration has culminated in the Training Seminars on the 5th October 2007 following the GHTF Conference, which will also be recorded onto DVD for future use in training sessions. The Pan American Health Organization (PAHO) also expressed a wish for their members to receive NCAR training on the 5th of October. Bjorn Fahlgren of WHO agreed with Dr. Garcia's introduction and noted that between 6 and 12 countries of WHO and PAHO member states were interested in attending the GHTF Conference and training afterwards.

The Steering Committee decided, upon the recommendation of Mr. Fahlgren, to invite representatives of Ministries of Health from Latin American countries to the Conference and the training afterwards. Study Group 2 will

modify its NCAR training, to reflect whether the participants expected to use the training to join NCAR or were attending for informational purposes. Mr. Fahlgren indicated he would like to contribute toward the training event in October. The Chair thanked Mr. Fahlgren for joining the meeting.

9.2 Standards Report

Mr. Wallroth reported on the Standard Activities.

International Electrotechnical Commission (IEC)/Subcommittee (SC) 62A Common aspects of electrical equipment used in medical practice

Mr. Wallroth said the IEC recommended the current proposed SG1(PD)N44, *Role of Standards in the Assessment of Medical Devices (revised)* document address the withdrawal of recognition and the impact that has on both products already in the market and previously approved products that are about to enter the market. This is particularly significant when a major revision of a horizontal product standard, such as IEC 60601-1:2005, is published.

Action Item: The Steering Committee discussed the recommendation and agreed to refer the question to Study Group 1.

IEC/TC62D, Electromedical equipment

Mr. Wallroth said the IEC reported that SC 62D is in the process of updating all standards within its work program to align them with the IEC 60601-1:2005 (edition 3). The SC has decided that Particular Standards that have not reached Committee Draft for Vote (CDV) stage by the end of 2008 will be withdrawn. This might lead to the withdrawal of IEC 60601-2-10 (nerve and muscle stimulators), due to apparent impossibility to reactivate Maintenance Team 18 Therapeutic Equipment.

IEC/TC 66, Safety of Measuring, Control and Laboratory Equipment and IEC/TC 87 Ultrasonics

Mr. Wallroth noted that IEC responded with the information that they have no concern to report.

IEC/TC 62 and IEC/SC 62B X-ray Equipment Operating Up to 400 KV and Accessories

Mr. Wallroth reported on IEC's concerns for consideration by the GHTF Steering Committee. The need for convergence of regulations addressing safety aspects of medical devices in various countries, e.g. the protection against ionizing and non-ionizing radiation is covered by regulations usually different from those regulations covering medical devices.

The Steering Committee said this concern was outside the scope of GHTF and GHTF was not the appropriate vehicle to communicate such concerns.

International Organization for Standardization (ISO)/Technical Committee (TC) 121, Anaesthetic and Respiratory Equipment

Mr. Wallroth said ISO reported that many of the existing and newer projects concern electrically powered medical equipment and this work is mostly done in cooperation with IEC/TC 62A and 62D by means of joint working groups. This cooperation is proving successful, although it is not without some administrative challenges due to lack of operating procedures for ISO/IEC joint working groups.

ISO/TC 150, Implants for surgery

Mr. Wallroth said that ISO reported "In past years we have benefited in TC 150 from the personal input in the standards writing process of experts from regulatory bodies such as the British MHRA. Unfortunately the need to make economies of expenditure have led to the withdrawal of participation by the British MHRA experts."

"Scientific progress has lead to the appearance of completely new classes of medical device and it is often unclear whether they should be viewed as an implant or as pharmaceutical product. The problem is most acute with tissue engineered products but also affects drug/device combinations such as vascular implants with a drug coating or impregnation. A new subcommittee has been formed in TC 150 to consider tissue engineered products and it will rely upon close co-operation with TC194. It is our impression that there is an unclear global regulation situation. Regulators in different parts of the world have widely differing views on whether they will use standards from the pharmaceutical or the surgical implant field to help them advise on new tissue engineered products."

Action Item: The Steering Committee asked Mr. Wallroth to inform ISO/TC 150 about GHTF's efforts concerning combination products. The Steering Committee requested that Mr. Wallroth request the scope of the work plan about tissue engineered products from TC 150 and TC 194.

ISO/TC 210, Quality management and corresponding general aspects for medical devices

Mr. Wallroth said that ISO forwarded a questionnaire on modifications to ISO 13485 or ISO/TR 14969 should be circulated to GHTF members for response by 5 June 2007. Results will be discussed at a joint meeting of ISO/TC 210/WG1 and GHTF/SG2 in Washington, DC on 3 October 2007.

"The GHTF needs to be aware that the ISO TB WG on Risk Management is revising Guide 73 on Nomenclature for Risk Management. This is intended to be an overarching guide and thus has the potential for greatly influencing the work of TC 210 with consequent effect on regulatory bodies. GHTF should consider what appropriate action is required."

"The JWG 1 on Risk Management for Medical devices is developing a white paper on "Guidance for Writers of Product and Process Standards on the use of a Risk Management Framework in Standards. The white paper is intended to serve as a basis for revising ISO/IEC Guide 63. The revised Guide 63 is intended to provide guidance for standards writers to facilitate the inclusion of safety aspects in the development of international medical device standards intended to be used within a risk management framework."

At the meeting of ISO/TC 210 WG3 with members of European Committee for Standardization /European Committee for Electrotechnical Standardization (CEN/CENELEC) Joint Technical Committee (JTC)3 WG1 on April 16, 2007, the process of merging ISO 15223-1 and Norme Européen (EN) 980 will commence.

The Steering Committee noted that Study Group 3 was having a joint meeting with ISO/TC 210 on 5 October 2007. Action Item: The Steering Committee decided to work through the Study Group 3 members, and urged Steering Committee members to forward their comments to Study Group 3. As a general policy, the Steering Committee prefers to avoid the duplication of standards.

ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems

Mr. Wallroth said that ISO reported that TC 212 is interested in exploring opportunities to cooperate with GHTF in developing international standards that further our mutual goals and interests. TC 212 looks forward to a continuing dialog and would welcome proposals for new work items in the areas that GHTF considers necessary to support the quality management systems of IVD manufacturers and medical laboratories.

The Steering Committee noted that Mr. Powers, the Chair of ISO/TC 212, is attending the GHTF's IVD Subgroup meeting this 7-10 May 2007.

ISO/TC 215, Health Informatics

Mr. Wallroth said that TC 215 draws attention to the agreement between CEN, ISO and Health Level 7 (HL7) on Coordination and Collaboration of October 10, 2006, Geneva and offered to send a report following the plenary

meeting of TC 215 in Montreal Quebec, 25 March 2007. (The Chair had requested members to report on the use of GMDN in their respective regions.)

Action Item: The Steering Committee decided to discuss infomatics at the October Steering Committee meeting. The Chair requested Regulators to report on the use of Infomatics in their respective regions.

9.3. CASCO and IAF

The Steering Committee discussed the two organizations and whether it was appropriate to pursue a relationship with either CASCO and/or IAF. CASCO sets standards for organizations that do conformity assessments, and accrediting bodies and auditing bodies. Members supported not duplicating the work of CASCO in Study Group 4, and suggested working with CASCO in establishing standards on how conformity assessment would be accomplished. Action Item: It was recommended that the Chair and Mr. Zobrist contact CASCO and invite them to become a Liaison Body.

IAF is a non-governmental organization that accredits organizations that do conformity assessments. Some members noted that establishing a liaison with IAF was premature and that it would be more appropriate to consider a relationship with IAF after CASCO established standards on conformity assessment. Some members expressed concern about having private organizations doing accreditation, and raised concerns about the ability of Regulators to accept the accreditation process implemented by non-governmental organizations where there was no Regulator oversight in the process of accreditation. Action Item: It was decided that it was premature to establish a relationship with IAF.

9.4. IEC Liaison Body Application

The Steering Committee considered and accepted the application of the International Electrotechnical Commission (IEC) to become a Liaison Body. Because of internal IEC processes, the relationship is through Technical Committee (TC) 62. Action Item: The Chair will verify that TC62 represents all of the IEC in this liaison relationship with GHTF.

10. Update of Main Developments for Liaison Bodies – AHWP

Dr. Pillay gave an overview of the Asian Harmonization Working Party's (AHWP) relationship with GHTF. AHWP became a liaison body member in October 2006. AHWP is working with Study Group 1 in the IVD area and trying to align with the STED. Their safety alert system is aligned with NCAR and they will participate with Study Group 2. The guidelines AHWP is developing are complaint with GHTF guidelines.

11. Planning of the GHTF Conference 2007 – Washington, DC

The Chair updated the Steering Committee on the Conference planning and early registration numbers. Members were urged to take advantage of the early bird sign-up savings.

12. Upcoming meetings

The Chair mentioned the upcoming meetings. First he mentioned the GHTF Conference, 3-4 October 2007, in Washington, DC, USA. He also discussed GHTF participation in APEC meetings, particularly the training of Latin America Harmonization Working Party members, 5-6 October 2007, in Washington, DC.

13. Next GHTF SC meeting

It was discussed that the monthly telephone conferences are worthwhile and should be extended to 90 minutes. The Chair mentioned the upcoming Steering Committee Meetings: (1) 30 September – 2 October 2007, Washington, DC and (2) the Regional Meeting 3-9 March 2008 in Kuala Lumpur, Malaysia.

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

14.1. Study Group 1

Dr. Michaud updated the Steering Committee on the work of Study Group (SG) 1. One main focus of SG 1 and the In-vitro Diagnostic (IVD) Subgroup has been expansion of the Study Group. Dr. Michaud touched on the continuing interest by non-founding members to participate in SG1. Those interested include non-member Regulatory Authorities and Industry Associations, and Standards Development Organizations. SG1 participants have expanded to include 2 from AHWP and Pacific Asia Conference on Mechanical Engineering **(**PACME). The IVD Subgroup has also expanded to include one AHWP delegate.

As a result of the participation of the AHWP delegates, SG1 achieved greater convergence between SG1 Summary Technical Document (STED) and the AHWP Common Submission Dossier Template Common Submission Dossier Template (CSDT), and the development and completion of SG1 STED document revision was accelerated. It is anticipated that this convergence and acceleration gave a greater voice to non-member participants that will benefit the nations of Association of South East Asian Nations (ASEAN).

SG1 and PACME have proposed a half-day joint meeting in advance of the 2007 GHTF Conference in Washington, DC. The joint meeting will serve as an introduction to the two groups. Two of the PACME delegates will join SG1 as permanent members.

SG1 continues its work on SG1/N011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles (STED).* The proposed document is under revision to become a final document. It is SG1's priority one document. The target date for completion is the second quarter of 2007.

SG1(WD)/N055R3 *The definition of the Term "Manufacturer" and Related Entities*. *).* The Working Draft is under development. It is SG1's second highest priority document. The target date for completion is the fourth quarter of 2008.

Registration of manufacturers and their medical devices by the Regulatory Authority is a joint Work plan with Study Groups 3 and 4. It is SG1's third priority. The target date for completion is the fourth quarter of 2008.

SG1(PD)/N045R12 *Principles of Classification of In Vitro Diagnostic Medical Devices* is a candidate for advancement as a proposed document. It is the IVD Subgroup's number one priority. The target date for completion is the second quarter of 2007. The document is presented to the Steering Committee after extensive discussion within the IVD Subgroup. Before proceeding to a Final Document, SG1 seeks comments on all aspects of its contents. In particular, they would like to draw attention to Rule 4 (Page 13) which Classifies devices as Class C devices if they are intended for either near-patient testing or self testing. Action Item: The Steering Committee endorsed the document. SG1(PD)/N045R12 as a proposed document to be posted for public comment.

SG1(PD)/N046R3 *Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices* is a candidate for advancement as a proposed document. The target date for completion is the second quarter of 2007. It should be read in conjunction with the GHTF document SG1(PD)/N045R3 *Principles of Classification of In Vitro Diagnostic Medical Devices*. Action Item: The Steering Committee endorsed the proposed document SG1(PD)/N046R3 to be posted for public comment.

SG1(WD)/N063/R1 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices*. It is the IVD Subgroup's second priority. The target date for completion is the fourth quarter of 2008.

Some of the IVD Subgroup members are currently working under SG5 on the development of IVD content for SG5 guidelines.

SG1 has also been working on the GHTF Study Group 1 Communications Database. The Database has 133 entries for Regulatory Authorities, Industry Associations, Notified Bodies and Notified Body Oversight Organizations, PAHO, and Standards Development Organizations. The goal is to be more

inclusive of parties not directly involved in writing the guidelines and to achieve broader input in public consultations. SG1 seeks input from the Steering Committee on the content and possible uses of the Database. Currently SG1 is using the Database to encourage public participation and the broad dissemination of GHTF information to interested parties. The Steering Committee supported use of the Database by other Study Groups as well.

The Chair thanked Dr. Michaud for her update. Action Item: The Chair also requested SG1 to review the Software Recommendations number 1, 2, 4 and 10.

14.2. Study Group 2

Dr. Garcia reported on the piloting of electronic reporting. It is a large and complex project. The project leader is Mr. Ekkehard Stosslein (BFaRM). SG2 expects that all SG2 regulators and all manufacturer representatives will need to participate in the pilot for some time before enough experience is gained through the pilot. SG3 is developing the software, perhaps an HTML document or Word document – that generates the XML coded files. Regulatory agencies participating in the pilot will need to write the "decoding" software that enables them to receive and display the information in a meaningful way. SG2 expects electronic reporting to begin by October 2007.

Dr. Garcia reported that the SC accepted Cuba's Centro de Control Estatal de Equipos Medicos (CEEMM)'s application to join the NCAR program in November 2006. Negotiations in relation to the extent and conditions of CEEMM's training have been proceeding slowly, but the problems are logistical in nature. CEEMM has said that they intend to participate in Washington if possible, but that they would still like to receive training in Cuba if at all possible.

Dr. Garcia said that the AHWP has approached SG2 for the provision of training to AHWP members that would enable them to join the NCAR program. It is expected that this training would take place following the AHWP meeting in China. The AHWP is also planning on establishing its own rapid alert system. The AHWP rapid alert system is still under discussion – it is not yet clear how the NCAR system and the proposed Asian rapid alert system will interact with GHTFs program.

SG2 identified that there is a need for NCAR participants to maintain knowledge and commitments. SG2 has decided to establish retraining program for existing NCAR members. SG2 expects to do this training in several ways concurrently (e.g. through information items sent through the NCAR mailing list itself, through discussion of issues at SG2 meetings, through the use of the DVD that will be created in October, etc.).

SG2 has begun reviewing the NCAR documents which will most likely lead to revisions of SG2/N38R15:2005 *Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program* and SG2-N79R8:2006 *Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.*

The Steering Committee asked SG2 to define "maintenance phase" at the same time it told SG2 to go into maintenance phase. SG2 has considered the Steering Committee request. SG2 believes that there is still significant and important work to be done by SG2. SG2 notes that it is meeting less frequently, but SG2 members are still quite busy with SG2 related work. SG2 finds that the term "maintenance phase" creates some practical difficulties, such as, members are having difficulty justifying travel expenditure to attend meetings of a group that is supposedly under "maintenance."

SG2 recommends that "Monitoring and Improvement Phase" is a better term to describe the current work of the SG2 and seeks the agreement of the Steering Committee to use it from now on. The Steering Committee thanked Dr. Garcia for his report and said it would take the SG2 recommendation under advisement.

15.3. Study Group 3

Mr. Cobbold presented SG3's work plan update. He said that SG3 continues its work on SG3(WD)N17 *Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers*. He also said that SG3 continues its work on SG3(WD) N18 *Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activities*. In addition, SG3 continues its work on SG3(WD)N19 *QMS deficiencies Quality Management System – Medical devices- Guidance on quality management system deficiencies*.

SG3 also continues its work in conjunction with SG4 on *Audit Suppliers* guidance. SG3 continues its work with SG1, 3 and 4 on the *Definition of Manufacturer* guidance. Mr. Cobbold informed the Steering Committee that SG3 will be working with TC176 on changes to ISO9001 and ISO13485.

SG3 would like to switch the priority of work of N19 and N18 and make N19 their first priority. Action Item: They were asked to float that proposal at the next telephone conference.

15.4 Study Group 4

Mr. Zobrist updated the Steering Committee about SG4's work. He noted that SG4 was working on SG4(PD)N33R13:N33 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports*, and that the comment period closes 15 June 2007. The Chair said that N33 is an important document because it provides the foundational structure for joint audits. Mr. Zobrist said that SG4 hoped to have

the document ready to be presented as a final document to the Steering Committee in October. The Steering Committee voiced their appreciation for SG4 push to finalize this document.

Mr. Zobrist also informed the Steering Committee that SG4's work on revising N28:1999 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers: – Part 1: General Requirements* was proceeding as well. SG4 was currently at the Working Draft stage of that revision.

15.5 Study Group 5

Mr. LeBlanc presented SG5/N1R8: *Clinical evidence – Key Definitions and Concepts* and SG5/N2R8: *Clinical Evaluation* to the Steering Committee seeking approval for them to be posted as Final Documents. The Steering Committee endorsed the two documents as final documents.

SG5(WD)/N3R2 *Clinical Investigation* was presented to allow the Steering Committee to review the progress. The Steering Committee had asked SG5 to present their Working Document at the May 2007 meeting. The Steering Committee suggested that SG5 consult with SG1 on conformity assessment and to help with the general approach on post market follow-up. Some members requested that the guidance be more fleshed out.

SG5 also proposed a New Work Item, *Post-Market Clinical Follow-Up for Medical Devices* to provide guidance on how and under what circumstances post-market clinical studies should be carried out in order to fulfil post-market obligations, particularly for those devices where identification of possible emerging risks and the evaluation of long-term safety and performance are critical. Action Item: The Steering Committee suggested that SG5 look at the SG2 documents as a first step. SG5 should continue their consultation with SG2 to ensure the scope does not duplicate the work of SG2.

SG5's next meeting will be September 2007.

15. AOB

15.1. Recalls

Mr. Kraus proposed improving the communication of Class I recalls (may cause serious injury or death) amongst regulators. He suggested that a Class I recall in one jurisdiction had a chain reaction. Upon hearing of a Class I recall in one jurisdiction, politicians and regulators received inquiries about whether a similar action would be needed in their jurisdiction. He suggested harmonizing to a single communication that could be shared. Mr. Gropp suggested using the term field safety corrective action, because of the emotional response to the word,

recall. He further suggested that industry had an important role in communicating the field safety notice. Mr. Kelly noted that identifying what procedures or documents that need to be in place to have such communication should be addressed. It was suggested that it would be useful to have a portion of the GHTF website where Regulators could place communications. Dr. Pillay suggested that the ASEAN communication system under development may serve as a model for this communication system.

The Steering Committee decided on a two prong proposal. First to check with Study Group 2 regarding what they are writing about field safety actions. Secondly prepare what needs to be in place to communicate the information. Action Item: Mr. Kraus, Mr. Gropp and Mr. Kelly volunteered to draft a paper to be presented at the next Steering Committee meeting.

15.2. Study Group Work Timeframes

After reviewing some of the work plans of the SGs a discussion ensued among Steering Committee members about the timing of working on documents and whether 18 months was too challenging a timeframe for completing work on a document. The discussion touched on the prioritizing of documents, and the wisdom of giving a document a high priority, when the SG knows it cannot begin work on the document for several months. It was noted that work may be difficult to complete if the SG did not have its full complement of participants or the SG did not meet frequently enough to finish the work more quickly due to budget constraints of members. It was also noted, that given the flow of work and the frequency of Steering Committee meetings, SGs found it productive to moving forward with work to have a few new work item proposals in the queue to ensure there was no lag time in starting a project. Action Item: The Steering Committee agreed that this topic would be appropriate for discussion at an upcoming Steering Committee telephone conference.

15.3. Study Group Chairs Telephone Conferences Recommendation

The Steering Committee recommended that the Study Group Chairs should establish periodic conference calls among the Chairs to discuss best practices, alternate meeting procedures, and other pertinent issues. Study Group Chairs should also consider having Study Group meetings by phone or other means, in addition in-person meetings.

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