

GHTF STEERING COMMITTEE

Meeting Minutes

**The Ronald Reagan Building
and International Trade Center,
1300 Pennsylvania Ave., NW,
Washington, DC**

30 September* – 2 October 2007

(* **30 September** - Industry and regulators met separately in the morning at the offices of Advanced Medical Technology Association (AdvaMed) for that purpose. The Steering Committee met in the afternoon at the offices of AdvaMed, 701 Pennsylvania Ave., NW, Suite 800, Washington, DC.

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, Hiroshi Yaginuma, Shigetaka Miura and Hiroshi Ishikawa from Australia, Rohan Hammett, Anne Trimmer and Johan Brinch; from Europe, Laurent Selles, Marie-Lise Miguères, Mathias Neumann, Jos Kraus, Brian R Matthews, Christine Tarrajat, Nicole Denjoy, Carl F Wallroth,; from the Liaison bodies Mukundan.Pillay (AHWP); the Study Group Chairs Ginette Michaud, Egan Cobbold, Markus Zobrist and Susanne Ludgate; for the Liaison members Datuk M.S. Pillay and Norbert Bischof; for the Secretariat Jean Olson.

The Chair thanked the Vice-Chair and Ellen Bielinski for their hard work on the Conference.

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

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 12th 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 began by noting that GHTF has been conducting training on an ad hoc basis, and suggesting that it is appropriate to develop a plan for conducting training in the future. The Chair suggests that training is a good opportunity to be proactive and to target the audiences we wish to hear GHTF's message. He suggest establishing an ad hoc working group to fill in a plan and move forward the training agenda. He further suggests that GHTF may need other organizations to move forward the training agenda because of limited resources and could use help organizing the training and providing a mechanism to collect money.

The Training Strategy Discussion Paper that had been circulated earlier raised several issues including the relationship between training and GHTF participation; potential curriculum of GHTF training; training materials; trainers; how, when and where to conduct training; and resource issues.

Mr. Gropp noted that currently we are providing two forms of training: training on GHTF documents and training on programs like National Competent Authority Report (NCAR). Mr. Gropp suggested a first step would be to document and outline the global regulatory model. He questioned whether GHTF documents are developed to be reference guides or training manuals.

Discussion of how to promote the quality of training ensued. Issues discussed included the following: how to identify trainers; how to ensure the quality of trainers; how best to provide a coherent framework for training; should GHTF outline a proposed recommended curriculum; whether to be proactive or reactive with training and who is asking for training; whether GHTF wants its training program to be promotional, educational or interventional; whether the GHTF global model ready for use in emerging nations; or to what extent GHTF wants to dialogue with its audience.

In discussing how best to broadly promote implementation of the global model and global model training, it was considered if a permanent secretariat for training might be a possible solution. Members agreed that training content and message resided within GHTF.

Mr. Mathews suggested that training partners might be the best vehicle for providing structure to the training program. It was suggested that the Steering Committee should decide on the appropriate criteria for the partners. The advantage of working with non profit partners was discussed. Ms. Trunzo noted that any limits on cost recovery may limit the number of organizations interested in partnering with GHTF. Mr. Diebert suggested that an entity like a learning institute which used a business model to provide training might be a possibility. He suggested learning institutes may have greater expertise in locating more opportunities to economically provide training. Mr. Sweeney recommended utilizing a web based training model. He suggested that the economics of giving and receiving training on the web was more feasible.

The Chair, Mr. Diebert, Mr. Gren, Mr. Sweeney and Ms. Trunzo volunteered to be on the Training Ad Hoc Working Group.

Action Item: Dr. Pillay agreed to ask an AHWP member to participate in the Training Ad Hoc Working Group.

5.2. GHTF Website

The Chair gave a brief overview of the revisions to the GHTF website being instituted. He noted that there would be a Contact button on the main page and there was still a need to populate a number of the pages. He further noted that FDA continued to work on having a Members Only section. He noted that the first options reviewed by FDA were too expensive, but less expensive options were still being pursued.

5.3. Ad Hoc Working Groups – Proposed Changes to Operating Documents for possible adoption

Mr. Neumann and Mr. Gropp noted that the principals of the Ad Hoc Working Groups had been accepted by the Steering Committee and that it only remained to amend the *Roles and Responsibilities* document. Mr. Neumann and Mr. Gropp will forward the amended documents to the Steering Committee. They provided a flow chart that showed the Ad Hoc Working Group procedures graphically. Members raised the issue of the reporting mechanism for the Ad Hoc Working Groups. It was agreed that the Ad Hoc Working Groups should report at least six weeks before an upcoming meeting. The Steering Committee thanked Mr. Neumann and Mr. Gropp for their work.

Action Item: In a move to create more transparency, the Steering Committee agreed to post the Ad Hoc Working Groups on the GHTF website.

Action Item: Mr. Neumann and Mr. Gropp will forward recommended amendments to the Roles and Responsibilities document for Steering Committee review and approval.

5.4. Combination Products Ad Hoc Working Group

Ms. Maclachlan has agreed to continue to Chair the Combination Products Ad Hoc Working Group. She proposes that it meet in Brussels in December 2007 and she is working to arrange a venue. EUCOMED has offered to provide a venue. Ms. Maclachlan intends to email the details to the members and intends to draft a paper for the members to discuss. Mr. John Brennan, Mr. Gropp, Dr. Hammett, Mr. Dario Pirovano, Mr. Matthews, Ms. Trimmer, Ms. Trunzo, and Mr. Yaginuma volunteer or are volunteered to work on the Ad Hoc Working Group. Members suggest that the group consider nominating a Vice Chair to help with the workload.

Action Item: Ms. Maclachlan will email meeting details and draft paper to Ad Hoc Working Group members.

Action Item: Mr. Ulatowski will identify the FDA delegate to the Ad Hoc Working Group.

5.5. Software Ad Hoc Working Group

Dr. Brian Fitzgerald reported on a recent joint meeting with Study Groups 3 and 4 about the Software Ad Hoc Working Group recommendations. The Software Ad Hoc Working Group and Study Groups 3 and 4 set in motion a plan to liaison with the Study Groups to keep the Study Groups fully informed. The Software Ad Hoc Working Group said that it sees their Ad Hoc Working Group as subservient to the Study Groups. The next step was to mark-up existing GHTF documents to indicate to Study Groups where the Ad Hoc Working Group recommends changes. The Software Ad Hoc Working Group would also be investigating the need for separate auditing for software (3 areas of software: software as a device, devices run by software, software that creates a device). Dr. Fitzgerald noted that some GHTF documents specifically exempt software validation. The Steering Committee asked the Software Ad Hoc Working Group to check on the work of ISO and IEC committees.

5.6. GHTF's Operations

Dr. Hammett opened by saying that the discussion paper was not intended to be seen as a criticism of previous GHTF Operations. He stated that the Paper was a thought piece to encourage a move to next stage of development, to generate discussion, and to move forward action items. Issues the Paper addressed include the following: timely production of documents, prioritisation of work activities, model target audience, appropriate type of work for Study Groups to do, performance measurements, and resource management. The Steering Committee members thanked Dr. Hammett for producing the discussion Paper and expressed support for addressing the issues it raises.

Maintenance issues included need for a GHTF document review and revision process with a well defined review and public comment schedule. However Study Group Maintenance Mode remained to be addressed. Members suggested using the Standards model, and leave a small group in maintenance mode, smaller than the entire Study Group. Members discussed whether the review group would be an Ad Hoc Working Group reviewing all documents on a scheduled basis, and assessing the need to have them revised, or have a subgroup of each Study Group reviewing its own documents on a scheduled basis.

Members discussed that the global model issues that they need to address include the need to prioritize the work and to target an audience for the global model. Members discussed to what extent is GHTF to continue focusing on Founding Member harmonization and to what extent should GHTF focus on model implementation? Members noted that interim steps to Founding Member harmonization builds confidence. Members noted that confidence building is between regulators, and between regulators and industry.

Members began to discuss best mechanisms to address emerging issues. Issues members raised include are Ad Hoc Working Groups a better way to address horizontal medical device issues? Members noted that currently most of the work is done by the Study Groups. Members noted that the Steering Committee was taking on more work with the emergence of Ad Hoc Working Groups. To manage the work more efficiently,

members suggested there was a need to have metrics for Study Groups, Ad Hoc Working Groups and the Steering Committee. Members touched on whether the Steering Committee needed to change its project management process, keeping in mind the GHTF members are volunteers, not employees. Members suggested that the Steering Committee needed to provide greater oversight. Member suggestions included that the Steering Committee should step in to help with conflict management and resource inadequacy. Members also suggested that the Steering Committee should be more engaged in the process of document production. Members questioned what were the process improvements that needed to be put into place to preserve resources and what kind of business process/metrics may be useful to adopt? Members suggested it would be useful to include comparison analysis to how ICH and PICS operate.

Timely production of GHTF documents was another issue raised by members.

Steering Committee agreed to form a number of Ad Hoc Working Groups to address these issues.

Global Model Ad Hoc Working Group:

Chair – Mr. Ulatowski

Participants: Mr. Brinch, Mr. Ishikawa, Mr. Kraus, Dr. Rotter, Mr. Sweeney, and Mr. Schoenbuehler/Ms. Denjoy

Maintenance Mode Ad Hoc Working Group:

Chair – Mr. Neumann

Participants: Ms. Costello, Dr. Garcia, and Ms. Trunzo.

Action Item: Consider adding another Study Group Chair

Process Improvements Ad Hoc Working Group:

Chair: Mr. Kelly

Participants: Ms. Trimmer and Mr. Yaginuma

Action Item: Ad Hoc Working Group Chairs are to write mission statements and submit to GHTF Secretary as soon as possible.

5.7. Translation Paper

The paper raised the following issues for discussion. (1) What criteria the GHTF should follow to determine the priority ranking for the translation of GHTF documents and into which languages? (2) How should the GHTF encourage countries or organizations in regions which would utilize the documents to translate them into their official languages? (3) How should GHTF assure the quality and integrity of translated documents?

After discussion, the Members agreed that GHTF did not want to be in the business of translating documents because of the resource cost involved would be too great. The members reaffirmed that English was the official language of GHTF documents. However, members also wanted to have links to outside organizations such as Pan American Health Organization (PAHO) or Asian Harmonization Working Party

(AHWP) that have translated some of the GHTF documents. It was also noted that Japanese industry had also translated many of the GHTF documents.

Action Item: The Chair will draft an appropriate disclaimer for the website to indicate when visitors are leaving the website for websites that have translated GHTF documents.

5.8. Global Medical Device Nomenclature (GMDN) Update

Mr. Maurice Freeman described the history of GMDN. Mr. Freeman said that GMDN would be meeting with US National Medical Library (NML) to explore the possibility of obtaining support on a more stable basis. The members praised Mr. Freeman for the quality of the product GMDN has produced and the work he and his small staff had accomplished. Members asked Mr. Freeman to address some transparency concerns they had about the holding company structure of GMDN. Mr. Freeman agreed to provide more transparency.

5.9. Proposal to Recognize Participants Work

The Chair would like to recognize work of GHTF participants by issuing thank you letters to individuals and their bosses. The Chair seeks guidance from Steering Committee members and Study Group Chairs to nominate appropriate participants as work progresses in upcoming months. The Steering Committee concurred with the Chair's proposal.

5.10. UDI

Dr. Jay Crowley noted that FDA had begun to transform its postmarket program. Part of that effort includes ensuring the quality of postmarket data. The Chair added that Medical Device Reporting reports (MDR) were completed by busy medical doctors and nurses. FDA believed Unique Device Identifiers (UDI) helped with the reporting process by making it easy to identify the device in question. Congress had directed FDA to draft a regulation on UDI for medical devices. FDA wanted to adopt a UDI system that was readable by humans, was readable by machine, was sensible, utilized presently available methods and minimized burden where practical. FDA met with industry organizations (AdvaMed and MITA) on the subject. FDA had also been working with the Therapeutics Goods Administration (TGA).

The Chair noted that FDA would like to have a meeting in the near future with the Regulator members of GHTF to discuss UDI. FDA would like to create a system that other regulators can adopt or that would not conflict with the programs of other member Regulators, so it would be helpful to have discussions with regulators prior to proposing any regulations. FDA will be contacting the Regulator members about a meeting.

6. Update of Main Developments in Founding Members Regulatory Systems (Members are invited to inform about ongoing developments)

JAPAN

Ms. Tawaragi notes that its guidance on donor selection criteria is final. A number of university hospitals do such studies to confirm safety of devices for life threatening conditions.

MHLW is also revising its guidance to clarify its regulations applying to bioventure companies and biotechnology products. MHLW intends to issue the final guidance by the end of 2007. Biotechnology products can be regulated as either medical device products or as pharmaceutical products, depending on the primary mode of action of the product. If the product is applied to skin or hair, MHLW regulates it as a medical device.

AUSTRALIA

Dr. Hammett noted that Australia had been moving to form its joint regulating agency with New Zealand (ANZPA) when the New Zealand legislature announced it would not be proceeding with legislation.

On 16 July 2007, the New Zealand State Services Minister Annette King announced that "The Government is not proceeding at this stage with legislation that would have enabled the establishment of a joint agency with Australia to regulate therapeutic products." She further advised that "The [New Zealand] Government does not have the numbers in Parliament to put in place a sensible, acceptable compromise that would satisfy all parties at this time. The Australian Government has been informed of the situation and agrees that suspending negotiations on the joint authority is a sensible course of action. "

Australia and New Zealand expect that the work that has gone into establishing the joint scheme will not be lost.

Australian Therapeutic Goods Administration (TGA) and New Zealand Medicines and Medical Devices Safety Authority (Medsafe) Officials in each country will now take stock of the work done to date with a view to identifying a course forward.

New Zealand does not currently regulate medical devices. It is possible that discussions may be reinitiated in the future. TGA is disappointed that the joint regulation will not be taking place. Australia is moving forward by identifying ways of improving regulatory frameworks.

Dr. Hammett says Australia is having an election, a new government should be in place by January 2008. Australia will be focusing on postmarket issues as well as in vitro diagnostic and biological regulatory frameworks.

Dr. Hammett notes that Australia continues with its devices transitioning into the GHTF regulatory model. Many devices have no problems transitioning. However, products that need reclassification have more trouble transitioning.

CANADA

Dr. Rotter notes that Canada's minority government could also be going into an election soon. Canada's parliament still has a bill before it asking that Health Canada produce a list of medical devices that do not contain phthalates. Health Canada estimates it will take 3 FTEs at least 2 years to gather such information. Health Canada should be

announcing management changes this week, including a new Assistant Deputy Administer. Health Canada has proposed to have cost recovery on all regulated health products. The User Fee act should be considered by Parliament in November 2007. Health Canada continues with its comprehensive review of all program areas.

Because regulation of reuse of medical devices would require a revision to Canadian law, Dr. Rotter noted it was decided to regulate reuse on a regional basis. Health Canada would lead the group of representatives from the regions of Canada to address regulating reuse.

Dr. Rotter added that Health Canada is revising its clinical trial regulations to harmonize more with other jurisdictions.

Dr. Rotter says that Health Canada continues its Pilot Multipurpose Audit Program (PMAP) with US FDA. Health Canada's MOU with TGA is moving forward with one outstanding issue – recognition of equivalent of quality certificates.

EUROPEAN UNION

Mr. Sellès informed that in the EU the revision (Directive 2007/47/EC) of the medical device directives will be fully implemented by the 27 Member States in March 2010. The European Commission has already begun reflection on a possible future recast of these directives to be proposed to the European Parliament and Council. Key issues include further convergence, new approach and the Blood Derivative Directive. The EC also wants to address any gaps for medical devices that consist of or are combined with human tissues and cells. Software is now part of the definition of medical devices. In 2008, the EU delegation to GHTF-SC will change: Dr. Ruocco, from Italy will replace Mr. Jean-Claude Ghislain of France.

UNITED STATES OF AMERICA

Mr. Ulatowski notes that FDA continues to work with Health Canada on the Pilot Multipurpose Audit Program (PMAP). FDA is at the earliest stages of working with the EC to try and pilot PMAP in Europe. However, more industry interest in the Canada/US PMAP will be needed before it can proceed in Europe. CDRH has begun a series of initiatives that will focus on postmarket activities including developing data systems, enhancing risk/benefit communication efforts, and collaborating on enforcement strategies and outcomes.

FDA is piloting quantitative decision making processes to use postmarket experience to inform the premarket decisions. It will attempt to structure a common framework to adjust risk benefit analyses at the premarket stage.

Mr. Ulatowski noted that Medical Devices User Fee Modernization Act (MDUFMA) II included changes to fee amendments, third party review of premarket notification, registration, filing of lists of drugs and devices, e-registration and listing, report by GAO, UDI, frequency of reporting for certain devices, inspections by accredited persons, nosocomial infections studies, and report on labeling regarding tanning and cancer.

Mr. Ulatowski adds that FDA intends to begin publishing FDA guidance documents in 2008 that will indicate the extent of adoption of a GHTF document. FDA hopes to address several GHTF documents in 2008.

7. Update of Main Developments for Liaison Bodies

7.1. Asian Harmonization Working Party (AHWP)

Dr. Pillay noted that AHWP's next meeting was in Chengdu, China, 23-27 October 2007. He invited GHTF members to the meeting in Chengdu. GHTF would be providing NCAR training in Chengdu. Dr. Pillay added that China and India are supporting AHWP.

Another AHWP meeting would be the week of 3-9 March in Kuala Lumpur, Malaysia. Dr. Pillay noted that currently GHTF was looking to do a 2 to 2 ½ day Steering Committee Meeting, a Joint meeting with AHWP, and then 2 to 3 days of training, with funds provided in part by APEC. Mr. Gren noted that there was a minor subsidy available for trainers.

Dr. Pillay said that AHWP's work with GHTF's Study Group 1, was aligning the Common Submission Dossier Template (CSDT) with the STED document. The final CSDT proposal would be presented in Chengdu. Dr. Pillay added that Association of South East Asian Nations (ASEAN) had been given a mandate to harmonize with the GHTF documents by 2010 and to use GMDN.

Dr. Pillay added that AHWP has initiated a structured Continuous Professional Development (CPD) program on medical device regulations at certificate and diploma levels, which will be conducted in collaboration with Hong Kong University and Northeastern University, USA.

7.2. International Electrotechnical Commission (IEC)

Dr. Bischof began by replying to questions asked him in the Standards Report.

Dr. Bischof noted that IEC can use dated or undated references in standards, although dated references were desirable. IEC rules indicated that undated references should be used. However, Technical Committees should resolve among themselves the preferred reference, based on preventing manufacturer mistake.

Dr. Bischof also noted that there was no current policy about joint work of IEC and ISO on the Medical Device Directives.

Dr. Bischof noted that IEC believed that rules about transitional periods on the application of a standard should be left to regulatory authorities in a country. It continued to be IEC policy to not set transitional periods.

Dr. Bischof also noted that it would be useful if a country's application of a standard deviated from international standards, the text was highlighted, or a list of deviations was attached.

Dr. Bischof said that IEC was working on a proposal about the refurbishment of medical equipment and considering a Plug and Play standard.

Dr. Bischof noted that TC62 had considered the GHTF request to compare ionizing radiation regulations.

8. Cooperation with international bodies

8.1. Standards Report

Mr. Wallroth raised the issue of a Delta list for international standards. This issue was referred by the International Electrotechnical Commission (IEC) Technical Committee 62 to the Global Harmonization Task Force (GHTF) Steering Committee. It was noted by IEC-TC62 that, in some countries, deviations from international standards were reported transparently in a “delta” list. It was explained that this transparent reporting was aimed at preventing significant divergence of international standards over time. After discussion, the Regulators decided to take the question home with them so that they could obtain feedback from their national standard setting bodies in their respective countries. Regulators wanted Standard Developing Organizations in their regions to inform GHTF’s decision.

Mr. Wallroth noted that IEC TC62 has asked GHTF to provide leadership in preventing redundancies in the health care software standards because many groups are developing standards or guidance in this area. The Chair noted that FDA does not support duplicative efforts and suggested that the Software Ad Hoc Working Group and the Study Groups be aware of this issue.

Mr. Wallroth also noted that joint IEC and ISO work item proposal on “Plug & Play” interoperability of medical devices on Patient-centric Integrated Clinical Environment part 1: general requirements for network control voting close date was 21 December 2007.

Dr. Wallroth then reviewed the updates from IEC/SC62D, ISO/TC84, ISO/TC121, and ISO/TC121 SC3, CENELEC/TC 62 and AAMI/Human Factors Engineering Committee for the Steering Committee.

8.2. Health Technology Assessment International (HTAi)

Mr. Reiner Banken of HTAi thanks GHTF for inviting him and began his presentation concerning Health Technology Assessment. Mr. Banken began by noting the WHO resolution from 2007 on Health Technology assessment. HTAi is a voluntary association of over 1000 members from over 50 countries who create and use HTA. HTAi includes thirty six organizational members from the for-profit and not-for profit sectors of the health care industry.

HTAi would like to discuss exchanging information, and possibilities for collaboration on promoting the concept and practice of obtaining optimal benefit from medical devices and related projects, which is why HTAi seeks to become an observer on GHTF Steering Committee.

A discussion ensued with Mr. Banken and the Steering Committee members clarifying the role HTAi took in producing health technology assessments and clarifying the kinds of information that GHTF had that was of particular interest to HTAi – clinical data was mentioned. The Chair thanked Mr. Banken for his presentation and noted that GHTF would respond to HTAi’s request in writing. During the discussion Dr. Hammett

noted that while Australia would be using health technology assessments in its regulatory considerations, Australia was unable to use cost considerations in its assessments. The Chair noted that health technology assessment was outside the US FDA mandate.

8.3. Pan American Health Organization (PAHO)

Mr. Antonio Hernandez began his presentation with a brief summary of medical device regulation in Latin America and the Caribbean. He noted that 32 country offices formed part of a regional framework, with medical device regulation as a recent addition. Regulatory issues that were of interest in Latin American and Caribbean countries included the following issues.

- New Technologies
- Competitive Global Market
- Marketing of Used and Refurbished Equipment
- Donation of Medical Equipment
- Reuse of Single-Use Devices
- Complex Clinical Procedures in Physicians' Offices
- Increased Use of MD at Home
- A Better Informed Population
- Need to Register Devices
- Tracking of Adverse Events and Recalls of Medical Devices
- Weak Post-Sale Service Support

While each country was acting on its own, Mr. Hernandez noted that the countries were also working in blocks to harmonize regulatory requirements in the region. GHTF documents help in the effort to harmonize. PAHO has been translating GHTF final documents into Spanish and Portuguese. Like the GHTF founding members, Latin American and Caribbean regulators find it easier to harmonize prospectively, rather than retrospectively.

The Chair thanked Mr. Hernandez for his presentation and noted that GHTF looked forward to future collaboration with PAHO. In particular, PAHO participation in Study Groups and planning for upcoming training, especially NCAR training were mentioned.

8.4. International Accreditation Forum (IAF)

Mr. Robert King began his presentation by thanking GHTF for the opportunity to address GHTF. Mr. Harvey Rudolph and Mr. Paul Brooks also representing IAF accompanied Mr. King. IAF is a member organization of 47 accreditation bodies (ABs), plus associate members. IAF provides guidance for ABs, provides a forum for technical committees, and provides oversight for Multilateral Recognition Arrangement (MLA) members. ISO 17024 requires auditor certification. ISO 17011 requires that accreditation and certification of auditors be separate and that accreditation be from a legal entity.

In the US, ANSI-ASQ National Accreditation Board (ANAB) was created to serve conformity assessment needs of business, certification bodies (CBs), and interested parties. IAF audits ANAB.

The Chair thanked Mr. King for his presentation and a discussion ensued between Steering Committee members and Mr. King to clarify their understanding of the role of IAF accreditation process and its relationship with CASCO. (Mr. King informed the Steering Committee that IAF was a member of CASCO.) Mr. King noted that IAF envisioned liaisoning with GHTF through Study Group 4. The Chair ended the discussion by noting that GHTF would be in touch with Mr. King.

8.5. Regulatory Affairs Professionals Society (RAPS) Liaison Body Application

Dr. Sherry Keramidas began her presentation by thanking GHTF for inviting her. She noted that RAPS was a professional society representing RA professionals as engaged in health products sector with more than 12,000 individual members in 53 countries. Sixty percent of RAPS members are involved in medical devices. Its mission was to promote a clear identification for RA professionals and setting standards for knowledge, competency, and skill. In addition to a general certification system, it also has more directed certification systems in the US, Canada and the EU.

The Chair began the discussion by thanking Ms. Keramidas for her presentation. Dr. Keramidas noted that RAPS was a training provider, and it was a way to widen the array of professionals exposed to GHTF training. Training could be done at seminars or on-line. Also, RAPS provided an opportunity to gather feedback on the training and trainers, which would allow GHTF to refine its training. RAPS had partnered with other organizations around the world to present training. RAPS was non-profit, so it works on a cost reimbursement model. This mechanism should help keep the cost of training within the reach of locals.

Dr. Keramidas explained that Liaison Body membership may not be a perfect fit for RAPS in terms of liaisoning with GHTF. However, it was the best available fit in GHTF's operating documents for the relationship RAPS wanted with GHTF. The Chair thanked Dr. Keramidas and RAPS for approaching GHTF with their proposal and for presenting many interesting possibilities for training opportunities. The Chair noted that GHTF would reply to RAPS application in writing.

8.6 WHO

Mr. Bjorn Fahlgren updated the Committee on WHO's current efforts regarding medical devices, particularly priority medical devices. He also touched on the on-going efforts of WHO and GHTF to establish a MOU, and to join efforts in training and nomenclature areas.

9. Upcoming meetings

9.1. GHTF Steering Committee Meeting, 3-9 March 2008, Kuala Lumpur, Malaysia

The Chair updated the membership on the planned regional meeting in Kuala Lumpur, Malaysia. The Chair noted that there would be a joint meeting with AHWP, and that the Steering Committee meeting would be followed by 3 days of training.

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

10.1. Study Group (SG) 1

Dr. Michaud updated the Steering Committee on the work of Study Group (SG) 1. SG 1 has expanded its membership to include participants two from AHWP, as well as two participants from Pan American Cooperation Medical Equipment (PACME) and Latin American Industry. SG 1 is having a joint meeting with Latin American delegates in October 2007.

Dr. Michaud discussed SG 1's work plan with the Steering Committee. First, Dr. Michaud discussed SG 1's priority 1 documents which SG 1 proposed to advance as final in the fourth quarter of 2007. The priority 1 documents included SG1(PD)/N011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles (STED)* and SG1(PD)/N044 *Role of Standards in the Assessment of Medical Devices*.

Dr. Michaud also discussed SG 1's priority 2 working draft documents which SG 1 proposed to advance as proposed documents in the fourth quarter of 2008. The two working draft documents were SG1(WD)/N055 *The definition of the Term Manufacturer and Related Entities* and SG1(WD)/N055 *The definition of the Term Manufacturer and Related Entities*.

Dr. Michaud discussed SG 1's In Vitro Diagnostic Medical Devices priority 1 documents which SG 1 proposed to advance as final in the second quarter of 2008. The two are SG1/N045 *Principles of Classification of In Vitro Diagnostic Medical Devices* and SG1/N046 *Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices*. For the priority 2 document, SG 1 proposed to advance as a draft document in the fourth quarter of 2008 the *STED for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices* document.

Dr. Michaud noted that the priority 3 documents (Definition of Medical Devices, Essential Principles, and Labelling), were 3 documents to be revised. SG1 hoped to revise the documents by the close of the second quarter of 2009.

Dr. Michaud brought the SG1/N044 *Role of Standards in the Assessment of Medical Devices* to the Steering Committee for approval as a final document. SG 1 revised the proposed document by expanding the scope to include in vitro IVD medical devices and provide guidance on the use of recognised standards that have been superseded. Dr. Michaud noted that the proposed document was posted in December 2006 and that 41 comments had been received and resolved.

The Steering Committee discussed transition periods needed for vertical and horizontal standards, and mandatory and voluntary standards impact on transition periods. It was decided that transition periods should remain a regulatory issue to be decided by the jurisdiction.

Action Item: The Steering Committee asked SG 1 to insert language that was not prescriptive about transition periods length, and forward the document for consideration again for approval as final.

Dr. Michaud also explained that a fundamental question had arisen concerning the STED. Whether the STED was a living document, or a snap shot in time? After discussion it was suggested that SG 1 consult with SG 3 and SG 4 about the question. However, it was noted that GHTF need the STED to become a final document.

A further question arose over the timing of the IVD Subgroup meeting, because Dr. Michaud had said there would not be sufficient time to work on comments between the meeting and present a document for the upcoming Steering Committee meeting. The Steering Committee suggested that the IVD Subgroup consider shortening the comment period to allow it to complete its work more in coordination with Steering Committee meetings.

The Steering Committee congratulated SG 1 for its outreach to AHWP and Latin America.

10.2 Study Group (SG) 2

Dr. Garcia makes his presentation by telephone. Currently SG 2 is in Maintenance Mode. SG 2 is maintaining NCAR which includes the development and maintenance of training materials, handling of new applications for membership/training and review of performance. SG 2 continues its ongoing work electronic reporting for improvement of the reporting and exchange mechanisms. SG 2 takes on new work items as identified by the Steering Committee and proposed by SG 2 in its review of developments in products and regulations. SG 2 also continues its training on GHTF documents.

A discussion ensued by the Steering Committee about maintenance mode and the work of SG 2. The Steering Committee decided to take SG 2 out of maintenance mode. Members suggested that SG 2 form a subgroup to run NCAR. Further, Dr. Garcia was invited to participate on the Maintenance Mode Ad Hoc Working Group.

10.3 Study Group (SG) 3

Mr. Cobbold noted that SG3 workplan remains as it was shared in the May 2007 meeting. (SG 3 continues its work on SG3(WD)N17 *Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers*. SG 3 continues its work on SG3(WD) N18 *Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activities*. In addition, SG 3 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. SG3 will be working with TC176 on changes to ISO9001 and ISO13485.)

Mr. Cobbold noted that SG 3 continues its work on SG3(WD)N17 *Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers*. Mr. Cobbold said that SG 3 intends to complete stage 2 by the end of 2008. Currently N17 *Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers* is priority 1, with N19 *QMS deficiencies Quality Management System – Medical devices- Guidance on quality management system deficiencies* as priority 2 and N18 *Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activities* as priority 3. SG 3 intends to complete some work by telephone conference to keep work progressing in between meetings. SG 4 has nominated to 1 or 2 people to work on a guidance document to control suppliers.

Mr. Cobbold reported on the meeting with Dr. Brian Fitzgerald of the Software Ad Hoc Working Group. They created a memo to ask the Software Ad Hoc Working Group to revise and clarify their recommendations. It was explained that it was not part of SG 3 and SG 4's mandate to provide guidance on auditing of software because most software is software used in production, not as part of the medical device.

Action Item: The Chair asked SG 3 and SG 4 to enter a brief report into the minutes on the result of their meeting with the Software Ad Hoc Working Group.

10.4 Study Group (SG) 4

Mr. Zobrist began by noting that SG 4 need a replacement for Mr. Robert Turocy.

10.4.1 SG4(PD)/N28/R3 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements*

Mr. Zobrist noted that the ISO/CASCO standards will need to be incorporated into the document before it goes final. After brief discussion the Steering Committee agreed that this document should be posted as a proposed document on the website.

10.4.2. Revision Number R15 of Study Group 4's N33 document entitled: *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports*

Mr. Zobrist noted that SG 4 could not reach consensus on N33 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports* and asked the Steering Committee to repost the document as a proposed document and ask for comments on the issue of order of the elements. The Steering Committee discussed the issue and suggested that a change in language may clarify that the order was only recommended. It was decided to ask SG 4 to discuss this issue again during their current concurrent meeting with the Steering Committee meeting and report back to the Steering Committee if they could reach consensus on the issue. If SG 4 could reach agreement on the language, the Steering Committee agreed that the document could be posted as a final document.

10.5 Study Group (SG) 5

Dr. Ludgate presented the SG 5 update to the Steering Committee.

10.5.1. SG5(WD)/N3R5, *Clinical Investigation*

Dr. Ludgate noted that the Steering Committee had asked SG 5 to keep it updated on its progress on the *Clinical Investigation* working document. The document addresses the general principles for when to undertake a clinical investigation, the general principles for when a clinical investigation was needed, the general principles for designing a clinical investigation, the specific details design for clinical investigations and the ethical considerations for clinical investigations. Dr. Ludgate said that SG 5 hoped to complete the document at the October meeting.

The Steering Committee told Dr. Ludgate to carry on with the work and that they were pleased with the progress being made by SG 5.

Dr. Ludgate also informed the Steering Committee that SG 5 had formed a subgroup to address clinical IVD issues and that it would begin on those documents in 2008.

Dr. Ludgate ended her presentation by noting that SG 5 intended to go into maintenance mode by the close of 2008.

11. AOB

12. CLOSED SESSION

Action Item: To increase the communication within GHTF, Study Group Chairs should have a routine telephone conference on at least a quarterly basis.

Action Item: Regulators should have the opportunity to obtain feedback from their regional SDOs on the Delta List issue. Regulators should forward a response on the delta list issue by the 13 December 2007 GHTF Steering Committee telephone conference.

Action Item: IAF Ad Hoc Working Group to bring a recommendation with options on exploring a relationship with IAF to the Regional Meeting in Kuala Lumpur.

Decision: Create the IAF Ad Hoc Working Group. Chair: Dr. Rotter. Members: Mr. Neumann and a few members from SG 3 and SG 4 to be selected.

Decision: Create HTAi Ad Hoc Working Group. Chair: Dr. Rotter. Member: Mr. Diebert. Mission to open a dialogue with HTAi.

Decision: Create GMDN Ad Hoc Working Group. Chair: Dr. Kessler. Members: Mr. Ishikawa, Ms. Trimmer and Ms. Trunzo. Mission to explore how best to work with GMDN.

Decision: To pilot sharing information on recalls among regulator founding members. Founding member regulators have agreements on sharing non-public information.

A simple process is proposed: 1) Each GHTF-Founding Member regulatory authority should designate a point-of-contact (POC) for these communications. 2) If a regulator would like to communicate non-public information on a serious public health issues, or request information on an issue, the regulator sends a confidential e-mail to the other

GHTF-FM regulator POCs, noting the issue and providing detailed information about the situation, product, and any actions planned or underway. Often NCAR reports indicate an issue with a device, or a regulator learns of an issue through other means. 3) If the regulatory authorities feel that they need to discuss or coordinate the action, a teleconference is set up among the regulatory authorities. 4) A further teleconference(s) may be desired to share additional information.

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