GLOBAL HARMONIZATION
TASK FORCE
Working Towards Harmonization in Medical Device Regulation

Secretariat
C/- Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
AUSTRALIA
Telephone: +61 2 6232 8666
Facsimile: +61 2 6232 8687

NOTE: These Minutes incorporate comments on the Draft Minutes provided by Steering Committee Members during June and July 2002; and will be endorsed at the Committee's 5th Meeting on 28 - 30 October 2002.

MINUTES

STEERING COMMITTEE - 4th MEETING

MEETING ROOM - JUPITER 2
3RD FLOOR
NOVOTEL APOLLO HOTEL
405 HAVELOCK ROAD
SINGAPORE

SUNDAY, 12 - MONDAY, 13 MAY 2002

AGENDA **PAGE NO.**

All current Matters for Study Groups 1, 2 and 4 are "matters arising from previous meetings" and have been included at Item 2 of the agenda.

The 4th Meeting of the Global Harmonisation Task Force (GHTF) Steering Committee was held in Meeting Room - Jupiter 2, 3rd Floor - Novotel Apollo Hotel, Singapore from Sunday, 12 - Monday, 13 May 2002 (as part of the 9th GHTF Conference).

Those present were –

Steering Committee Members:

Australia: Ms Rita Maclachlan (Chair) - Therapeutic Goods Administration
Mr Terry Slater - Therapeutic Goods Administration
Mr Brian Vale (Vice Chair) - Medical Industry Association of Australia

Japan: Mr Soichiro Isobe - Ministry for Health, Labor and Welfare - Japan;
Mr Masato Yoshida - The Japan Federation of Medical Devices Associations
Mr Kenichi Matsumoto- The Japan Federation of Medical Devices Associations

Canada: Dr Roland Rotter - Health Canada
Mr Kevin Murray - Medical Devices Canada

United States: Dr David Feigal Jr - Food and Drug Administration
Dr Lillian Gill - Food and Drug Administration
Mr Robert Britain - National Electrical Manufacturers' Association
Mr Michael Gropp - Advanced Medical Technology Association

Europe: Dr David Jefferys - UK Medical Devices Agency
Mr Rainer Voelksen - Swiss Federal Office of Public Health
Dr Bryan Allman - EUCOMED and European Diagnostics Manufacturers' Association
Mr Roland Gerard - EUCOMED.
Dr Carl Wallroth - EUROM VI
Mr Werner Schoenbuehler - COCIR

Observers: Mr Michael Chappell - Food and Drug Administration, USA
Mr Joseph Putzeys - European Commission
Mr Jos Kraus - The Inspectorate of Health Care, The Netherlands
Mr Kiyohito Nakai - National Institute of Health Sciences - Japan

SG Chairs: Mr Maurice Freeman, Chair - GHTF Study Group 1 (*)
Mr Kim Dix, Chair - GHTF Study Group 2 (*)
Dr Victor Dorman-Smith, Acting Chair - GHTF Study Group 3 (*)
Dr Markus Zobrist, Acting Chair, GHTF Study Group 4 (*)

Invited Guests: Mr Wong Yew Sin - Health Sciences Authority, Singapore and Asian Harmonization Working Party (*)
Mr Antonio Hernandez - Pan American Health Organisation (*)
Mr Shigetaka Miura - The Japan Federation of Medical Devices Associations
Ms Yoshiko Yamamoto - Quintiles Transnational, Japan
Mr Gerald Verollet - World Health Organisation (*)

Secretary: Mr Craig Davies - Therapeutic Goods Administration

(*) Present for parts of the Meeting only.

LIST OF ABBREVIATIONS

ADVAMED	Advanced Medical Technology Association
AHWP	Asian Harmonisation Working Party
CCAB	Centre Conference Albert Borchett
CDRH	Center for Devices and Radiological Health
CEN	European Committee for Standardisation
COCIR	Coordinating Committee of the Radiological and Electromedical Industry
EC	European Commission
EDMA	European Diagnostics Manufacturers' Association
EFTA	European Free Trade Association
EUROM VI	European Federation of Precision, Mechanical and Optical Industries
GHTF	Global Harmonisation Task Force
GMDN	Global Medical Devices Nomenclature
GMDN MAPG	GMDN Maintenance Agency Policy Group
HSA	Health Sciences Authority, Singapore
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
JFMDA	The Japan Federation of Medical Devices Associations
MEDEC	Medical Devices Canada
MHLW	Ministry for Health, Labor and Welfare - Japan
MIAA	Medical Industry Association of Australia
NCA	National Competent Authority
NCAR	National Competent Authority Report (NCAR) Exchange Program
NEMA	National Electrical Manufacturers' Association
PAHO	Pan American Health Organisation
RAPS	Regulatory Affairs Professionals Society
TGA	Therapeutic Goods Administration
UK MDA	United Kingdom Medical Devices Agency
US FDA	United States Food and Drug Administration
WHO	World Health Organisation

LIST OF ACTION ITEMS

Action Item	Status
1.4: GHTF Steering Committee Membership List and Contact Details Members to review the Steering Committee Membership List and advise any changes to the GHTF Secretary.	Referred to Members for noting, 21 June 2002
2.1: Global Medical Devices Nomenclature (GMDN) Maintenance Agency Policy Group Mr Freeman and/or Mr Don Boyer (GHTF representative to the MAPG) to keep the GHTF Steering Committee informed of any further developments and major outcomes achieved by the MAPG and forward their report/s to the GHTF Secretary for inclusion in future Steering Committee meeting agendas.	Referred to Mr Freeman, 21 June 2002
2.2: Review and Approval as a Final Study Group 4 Document *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)"* GHTF Secretary to present the SG4 document, *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)"* in final document format and post it on the GHTF website.	Completed, 3 July 2002
2.3: Implementation of the National Competent Authority Report (NCAR) Exchange Program GHTF Study Group 2 to complete its refined proposal on full implementation of the NCAR Exchange Program and the SG2 Chair to forward the updated proposal to the GHTF Secretary for inclusion in the agenda of the fifth Steering Committee Meeting.	Referred to SG2 Chair, 21 June 2002
The SG2 Chair to re-write the "Report on the SG2 Medical Device National Competent Authority Exchange Program - Pilot Phase" in a manner which would be suitable for posting on the GHTF website and forward the re-written draft to the GHTF Secretary for inclusion in the agenda of the fifth Steering Committee Meeting.	Referred to SG2 Chair, 21 June 2002
2.4: Update - Study Group 2 Work Plan As the program for the 10th GHTF Conference is being developed, the SG2 Chair to liaise with the incoming GHTF Secretariat to schedule a Workshop addressing SG2's 'progress to date' on its Postmarket Surveillance (PMS) project.	Referred to SG2 Chair, 21 June 2002
GHTF Secretary to present the four GHTF Study Group Work Plans in a standard format and post them on the GHTF website as agreed during the second and third Meetings (references - Steering Committee 2nd and 3rd Meeting Minutes, paragraphs 5.6.5 and 5.1.1.3 respectively).	Completed, August 2002
2.5: Consideration of <u>Two</u> Study Group 2 Documents (N31 and N33) as "Proposed Documents" GHTF Secretary to post the SG2 documents, "Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices by a Manufacturer or its Authorized Representative (N31R7.2)" and "Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (N33R10)" to the GHTF website as "Proposed Documents".	Completed, 11 June 2002
The SG2 Chair to forward the latest version of N33R10 to the GHTF Secretary for addition to the GHTF website as a Proposed Document.	Completed, 10 June 2002

2.6: Consideration of Four Study Group 2 Documents (N6, N20, N32 and N36) as "Final Documents" GHTF Secretary to post the SG2 document, "Comparison of the Device Adverse Event Reporting Systems in USA, Europe, Canada, Australia and Japan (N6R3)" on the GHTF website as a "Final Document", remove the document N6R2 and add a statement that "this document (R3) contains outdated information and readers are advised to consult with the Founding Member government websites to obtain the latest regulatory requirements".	Completed, 3 July 2002
GHTF Secretary to post the SG2 document, "Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria (N20R10)" on the GHTF website as a "Final Document".	Completed, 3 July 2002
Study Group 2 to review the documents, "Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3)" and "Medical Devices: Post Market Surveillance: Manufacturers' Trend Reporting of Adverse Events (N36R4)", in line with the current concerns raised by industry Members and forward revised versions of the documents to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 21 June 2002
3: GHTF Website Management GHTF Secretary to include hyperlinks on the GHTF website to the Founding Member industry association websites.	Completed, 24 June 2002
4.2: Americas Working Group GHTF Secretary to add the Spanish language versions of the GHTF Final Documents to the GHTF website and establish a hyperlink with the PAHO website - www.paho.org	Completed, 22 July 2002
GHTF Secretary to include the following issue in the agenda of the fifth Steering Committee Meeting - "Consideration of waiving GHTF Conference Registration Fees for representatives of Latin American and Caribbean regulatory authorities".	Noted by GHTF Secretary for next Meeting
5.1: Update - Study Group 3 The Study Group 3 Chair (or Acting Chair) to update the SG3 Work Plan to reflect the changes approved by the Steering Committee and forward the revised plan to the GHTF Secretary for addition to the GHTF website.	Referred to SG3 Chair and Acting Chair, 21 June 2002
6: Draft GHTF Strategic Plan: 2002-2007 The GHTF Vice-Chair to amend the Draft Strategic Directions document in line with Members comments outlined above and present the revised Document (8th Draft) during the GHTF plenary on 15 May 2002;	Completed, 15 May 2002
Following the 9th Conference, the GHTF Secretary to add the document to the GHTF website when all other conference presentations are being added; and	Completed, 17 June 2002
GHTF Secretary to include the Draft GHTF Strategic Directions document in the agenda of the fifth Steering Committee Meeting for further consideration of achieving/implementing the identified Tasks within specified timeframes.	Noted by GHTF Secretary for next Meeting
7: GHTF Training Following the receipt of any further comments by Members, Mr Brekelmans and Mr Gropp to update the Discussion Paper on GHTF Training and forward the revised version to the GHTF Secretary.	Completed, 3 July 2002
GHTF Secretary to distribute the document to all Members via e-mail for final comment and endorsement.	Completed, 4 July 2002
Once the paper is endorsed, GHTF Secretary to create a new 'GHTF training' section in the "General Information" page of the GHTF website and add the final version of the Discussion Document, in addition to information on any future training events, as the information becomes available.	Completed, 18 July 2002

Mr Brekelmans and Mr Gropp to prepare a Discussion Paper addressing the possible establishment of a GHTF Training Institute (for consideration in conjunction with the proposal to establish a GHTF Permanent Secretariat), and forward the paper to the GHTF Secretary for inclusion in the next meeting agenda.	Referred to Mr Brekelmans and Mr Gropp, 21 June 2002
8: Establishment of a Permanent Secretariat The Permanent Secretariat Working Group (chaired by Mr Gropp) to further investigate the feasibility of establishing a single permanent location for the GHTF Secretariat and report its findings to a future Steering Committee meeting for further consideration.	Referred to all Members (including Mr Gropp), 21 June 2002
9.3: Proposed Memorandum of Understanding between the GHTF and WHO The Chair to write to the WHO's Mr Gerald Verollet, as a follow-up to the preceding discussions concerning any on-going collaboration between the GHTF and World Health Organisation.	Completed, 26 July 2002
In order to pursue the establishment of a Memorandum of Understanding with the GHTF, Mr Gerald Verollet to arrange for the GHTF Chair to receive a formal request (or resolution) from the correct lines of authority within the WHO.	Referred to Mr Verollet, 26 July 2002
10: Regulation of Medical Devices containing Human Tissues The Steering Committee regulators to prepare written reports from their jurisdictions outlining progress to date on the regulatory approaches to medical devices containing human tissues.	Referred to Regulator Members, 21 June 2002
The Steering Committee regulators to forward their reports to the GHTF Secretary for inclusion in the agenda of the fifth Meeting.	Noted by GHTF Secretary for next Meeting
11: EUCOMED Global Standards Strategy Discussion Document Mr Roland Gerard to canvass Steering Committee Members to participate in the Global Standards Strategy Working Group and forward a report to the GHTF Secretary for inclusion in the next Meeting agenda, which outlines a proposal for further GHTF involvement in a global strategic healthcare standards group.	Referred to Mr Gerard, 21 June 2002
12: Medical Device Regulatory Responses to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) Mr Gerard to prepare a paper outlining any BSE/TSE issues which fall with the Steering Committee's purview and forward the paper to the GHTF Secretary for inclusion in the agenda for the next Meeting.	Referred to Mr Gerard, 21 June 2002
13.4: Retirement of Mr James Benson USA industry to advise the GHTF Chair of their nomination of a new member to the Steering Committee, to fill the vacancy that will be created on 30 June 2002 by Mr James Benson's retirement.	Request to nominate a new Member sent to AdvaMed, 4 July 2002
13.5: 10th GHTF Conference GHTF Secretary to add the dates and location for the 10th GHTF Conference to the "Conferences" page of the GHTF website.	Completed, 10 June 2002
In consultation with the incoming GHTF Chair, the incoming GHTF Secretariat to prepare a draft program for the 10th GHTF Conference and include this draft in the agenda of the fifth Meeting for consideration (in line with paragraphs 6.1 - 6.3 of the procedural document, *"GHTF Operating Procedures"*).	Referred to incoming GHTF Chair & Secretariat, 21 June 2002

ITEM 1: INTRODUCTION

ITEM 1.1: WELCOME AND APOLOGIES

1.1.1 The GHTF Chair, Ms Rita Maclachlan opened the Meeting and welcomed all Members to Singapore, for the fourth meeting of the GHTF Steering Committee and commencement of the 9th GHTF Conference. Ms Maclachlan expressed her sincere thanks and appreciation on behalf of the Committee to Dr Clarence Tan (Chief Executive Officer, Health Sciences Authority, Singapore) and representatives of the Local Liaison Committee for their significant assistance with helping to arrange the 9th Conference.

1.1.2 In particular, the Chair welcomed new Members, Dr Roland Rotter (nominated by Health Canada) and Mr Werner Schoenbuehler (nominated by COCIR) to their first Steering Committee Meetings. The Chair also advised she would be welcoming to the Meeting, Dr Victor Dorman-Smith and Dr Markus Zobrist who both agreed, at short notice, to deputise as the Chairs of GHTF Study Groups 3 and 4 respectively, for the duration of the Conference.

1.1.3 The following officials were also welcomed to the Meeting as observers, in place of the Members indicated -

- Mr Michael Chappell - Food and Drug Administration, USA (for Mr Dennis Baker);
- Mr Joseph Putzeys - European Commission (for Mr Cornelis Brekelmans);
- Mr Jos Kraus - The Inspectorate of Health Care, The Netherlands (for Mr Hanz-George Will); and
- Mr Kiyohito Nakai - National Institute of Health Sciences, Japan (for Mr Souichi Ikegaya).

1.1.4 Apologies were received from -

- Mr Souichi Ikegaya - Ministry for Health, Labor and Welfare, Japan;
- Mr Cornelis Brekelmans - European Commission;
- Mr Barry Evers-Buckland - Medical Industry Association of Australia;
- Mr Dennis Baker - United States Food and Drug Administration;
- Mr Hanz-George Will - Federal Department for Health, Germany; and
- Mr James Benson - Advanced Medical Technology Association.

1.1.5 Ms Maclachlan also welcomed the following guests to the Meeting, to observe and gain an understanding of the Steering Committee's functions and work items -

- Mr Shigetaka Miura - The Japan Federation of Medical Devices Associations; and
- Ms Yoshiko Yamamoto - Quintiles Transnational, Japan.

Under Japan's Chairmanship of the GHTF, Mr Miura will assume the role of GHTF Secretary-General and Ms Yamamoto will assume the role of GHTF Assistant Secretary.

1.1.6 As the Study Groups were meeting at the same time as the Steering Committee, the Chair advised that each of the Study Group Chairs would attend the meeting at various stages throughout the two days. The Chair also advised she had invited representatives from the Asian Harmonization Working Party, Pan American Health Organisation and World Health Organisation to join the meeting for Items 4.1, 4.2 and 9.2/9.3 respectively.

ITEM 1.2: ADOPTION OF AGENDA

1.2.1 Members accepted and adopted the items presented in the agenda for this meeting.

ITEM 1.3: MINUTES FROM THE 3rd STEERING COMMITTEE MEETING

1.3.1 The Minutes from the 3rd Steering Committee Meeting were included in the agenda papers and incorporated all comments received on the draft Minutes that were circulated on 13 November 2001.

1.3.2 Members were reminded the Minutes had been posted on the GHTF website on 30 January 2002. There were no further comments and the Minutes were subsequently ratified by the Committee as a true record.

ITEM 1.4: GHTF STEERING COMMITTEE MEMBERSHIP LIST AND CONTACT DETAILS

1.4.1 The Meeting's attention was drawn to the Steering Committee's membership list and contact details which were included among the agenda papers. The Chair asked all Members to review the list and advise the Secretary of any amendments or corrections which may be required.

Action:

Members to review the Steering Committee Membership List and advise any changes to the GHTF Secretary.

1.4.2 A Member sought clarification of the rules governing the attendance of observers and guests at Steering Committee meetings. The Chair advised the GHTF procedural rules state, "observers and advisers from the Founding Members may also attend Steering Committee meetings" (reference - *"GHTF Roles and Responsibilities"*, paragraph 6.1).

1.4.3 For operational efficiency and due to the sensitive nature of some Steering Committee discussions, Members agreed Meetings should generally be restricted to the 24 participants from the three geographic regions. Any requests for observers/guests to attend meetings should be directed to the Chair, and the Chair would generally grant permission in exceptional circumstances. If the Chair considered that attendance by a particular observer or guest was likely to cause any controversy, the Chair would seek the views of all Members before making a decision.

ITEM 2: MATTERS ARISING FROM PREVIOUS MEETINGS

ITEM 2.1: GLOBAL MEDICAL DEVICES NOMENCLATURE (GMDN) MAINTENANCE AGENCY POLICY GROUP

2.1.1 At the third Meeting, the Steering Committee reaffirmed its earlier view that the Global Medical Devices Nomenclature (GMDN) will be a major contribution to international harmonisation among regulatory agencies, particularly in vigilance and the worldwide registration of products.

2.1.2 Mr Maurice Freeman, Chair of the GMDN Maintenance Agency Policy Group (MAPG) provided the Committee with a detailed (verbal) report on the major issues discussed during recent meetings of the MAPG.

2.1.3 The Meeting was advised a report on the GMDN was published in November 2001 and the MAPG is currently considering a number of issues, including a mechanism for distributing the nomenclature, translation of the nomenclature and cost recovery, how to ensure the nomenclature is kept up to date, the establishment and costs for the Maintenance Agency/secretariat, etc.

2.1.4 The Committee also noted that final licences for use of the GMDN will be available in the near future and the MAPG has determined a cost structure for the nomenclature which will be based on a manufacturer's annual turnover, as follows -

- less than 10 million Euro - 1,500 Euro per year;
- 10 - 100 million Euro - 2,000 Euro per year; and
- greater than 100 million Euro - 2,500 Euro per year.

Private conformity assessment bodies will be asked to contribute 1,500 Euro per year and the MAPG has also decided to establish an Annual Charge for maintenance updates.

2.1.5 The MAPG have suggested the GMDN should be freely available to regulatory agencies, provided licence agreements are adopted. To assist with the on-going costs of the Maintenance Agency, the MAPG invites regulatory agencies to make an annual donation or sponsorship. The Maintenance Agency is 'not for profit' and all charges and donations will be used to ensure it is fully self funding. Members also noted the GMDN will be available in both hardcopy and electronically. A website is currently under development to facilitate electronic transfers.

2.1.6 Members asked whether there would be any review processes. Mr Freeman explained there would be and emphasised that every user will have the opportunity to highlight their needs to introduce new terms and/or question the need for any existing terms. Members noted there will be an on-going review process to ensure the GMDN is kept up to date.

2.1.7 Initially, a significant amount of review is required and it is anticipated the relevant expert group will have a high workload, particularly during the first 12 months of operation of the GMDN. Another on-going work item will be the development of new terminology as new technologies emerge. Mr Freeman explained these on-going review processes and subsequent updates of the GMDN will represent a significant component of the Maintenance Agency's costs.

2.1.8 In noting Mr Freeman's report, Members extended their thanks and congratulations to the MAPG on the achievements to date and requested that reports on further achievements and major outcomes be provided for discussion at future Meetings.

Action:

Mr Freeman and/or Mr Don Boyer (GHTF representative to the MAPG) to keep the GHTF Steering Committee informed of any further developments and major outcomes achieved by the MAPG and forward their report/s to the GHTF Secretary for inclusion in future Steering Committee meeting agendas.

2.1.9 At the third Meeting, all Steering Committee regulators undertook to carry out an evaluation of the GMDN within their own jurisdictions and provide reports on the outcomes to the fourth meeting. A summary of the reports provided by each of the five GHTF Founding Member regulators is outlined below.

Australia - the Therapeutic Goods Administration (TGA) believes the GMDN will satisfy Australia's requirements under its new regulatory system which will be implemented by 5 October 2002. The GMDN will form a base for defining a kind of medical device, will be utilised in vigilance exchange, in defining products in manufacturers' quality management systems and for inclusion of products in the Australian Register of Therapeutic Goods. The TGA will soon negotiate for a licence with the GMDN Maintenance Agency Policy Group.

Japan - the Ministry for Health, Labor and Welfare (MHLW) are aiming to harmonise its current nomenclature with the GMDN, but this will occur as Japan's new medical device laws are adopted. MHLW is currently awaiting consideration of new legislation by the Japanese Parliament. In the interim, MHLW are currently making the appropriate changes to definitions, classifications, generic names, etc. MHLW are planning to have a phase-in period for the GMDN from April 2003 to April 2005.

Europe - the European regulatory agencies are fully committed to the GMDN and its implementation. Introduction of the GMDN is very timely as it complements the existing vigilance and EUDAMED databases. The next stage of the process is for the European regulators to discuss the timing of implementation with the European industry.

USA - the FDA's Center for Devices and Radiological Health (CDRH) - plans to adopt the GMDN as a parallel system to their existing device classification scheme. The FDA currently has a smaller number of classifications than the GMDN - approximately 5,000, which are published in the Code of Federal Regulations. CDRH will aim towards transferring fully to the GMDN, but until this transition can be achieved, it will be necessary to operate two parallel systems.

Canada - Health Canada's current nomenclature system is essentially harmonised with the USA system. Health Canada plans to adopt the GMDN, but intends waiting until the system is operational in other jurisdictions. At this time, Health Canada will undertake a pilot study to ensure there are no problems prior to full implementation.

2.1.10 Members were pleased to note these reports, which demonstrate a commitment by all regulators to adopt the GMDN in a considered manner. In particular, the industry Members were encouraged to note all regulators moving in the same direction with this issue and welcomed the proposed transition periods.

2.1.11 However, it was reiterated that implementation of the GMDN should be a 'forward harmonisation' activity which is not applied retrospectively to adversely affect existing products. In acknowledging this point, some Members also noted that a point in time would ultimately be reached where transition periods must, for reasons of efficiency, be drawn to a close.

ITEM 2.2: REVIEW AND APPROVAL AS A FINAL STUDY GROUP 4 DOCUMENT - *"GUIDELINES FOR REGULATORY AUDITING OF QUALITY SYSTEMS OF MEDICAL DEVICE MANUFACTURERS - GENERAL REQUIREMENTS - SUPPLEMENT NO.4: COMPILATION OF AUDIT DOCUMENTATION (CLAUSE 5.7)"*

2.2.1 At the third Meeting, the Steering Committee gave further consideration to the Study Group 4 (SG4) document -

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)".

2.2.2 The Steering Committee agreed the document was primarily intended to provide guidance to auditors and was not intended as a tool to facilitate the transfer of information between regulatory agencies. In view of further concerns raised by USA industry Members, the Committee decided not to approve the document and requested that SG4 amend its scope and introduction to address the aforementioned point and the other issues previously raised by NEMA, and present the revised document to the fourth Meeting for further consideration.

2.2.3 SG4 considered the issues raised by the Steering Committee during its Singapore meeting. On 13 May 2002, the Acting SG4 Chair, Dr Markus Zobrist presented a revised document to the Committee for consideration and advised that consensus had been reached within the Study Group.

2.2.4 The USA industry Members advised their previous concerns had now been satisfied and the Chair noted that all Steering Committee regulators had previously acknowledged their acceptance of the document. The Committee therefore agreed that the document be approved as a Final GHTF Guidance Document and posted on the GHTF website in final document format.

Action:

GHTF Secretary to present the SG4 document, *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)"* in final document format and post it on the GHTF website.

ITEM 2.3: IMPLEMENTATION OF THE NATIONAL COMPETENT AUTHORITY REPORT (NCAR) EXCHANGE PROGRAM

2.3.1 At the third Meeting, the Steering Committee considered a proposal developed by Study Group 2 (SG2) on the implementation of the National Competent Authority Report (NCAR) Exchange Program.

2.3.2 The Steering Committee agreed that the draft document represented a 'blueprint' for full implementation of a NCAR Exchange Program, but also raised a number of issues, concerns and suggestions. The Committee asked SG2 to refine its proposal for further consideration at the fourth Steering Committee Meeting.

2.3.3 The SG2 Chair, Mr Kim Dix advised that the revision of the NCAR document is currently incomplete and asked for this item be carried forward to the fifth Steering Committee Meeting.

2.3.4 However, Mr Dix also advised that useful lessons had been learnt during the pilot and these have now been taken on board by the participating countries who have continued the system on an informal basis. SG2 continues to seek feedback from participating countries and in refining its proposal, is currently considering a two stage program, based on 'active exchange' and 'passive exchange' (with the latter being more of an information repository covering lower risk products while still providing a mechanism for information exchange).

2.3.5 Mr Dix also indicated the two major outstanding issues to be addressed by SG2 are mechanisms to allow for the inclusion of new countries in the program and how to balance confidentiality requirements vs ensuring public health and safety. Members reiterated some of their earlier comments and concerns relating to these issues.

2.3.6 Specifically, the new program must include a mechanism which ensures all 29 European countries are appropriately included. Members recalled it was previously proposed that the Steering Committee be the body that decides who the participants in any future program will be. This issue will be the subject of further discussion once the revised SG2 proposal is available.

2.3.7 Further, the program must also provide appropriate mechanisms or safeguards to ensure 'less experienced' countries do not inadvertently breach confidentiality requirements. As a possible way forward, a Member suggested that SG2 focuses on developing the most appropriate types of reports to circulate globally when medical device problems are reported (as opposed to focusing too closely upon who is / is not receiving and using the reports).

2.3.8 This suggestion is under-pinned by the notion, "if in doubt, circulate the report in the interests of public health". Members agreed, that when revising the proposal, SG2 needs to very carefully balance the public health and confidentiality issues which will be intrinsic to a fully implemented NCAR Exchange Program.

Action:

GHTF Study Group 2 to complete its refined proposal on full implementation of the NCAR Exchange Program and the SG2 Chair to forward the updated proposal to the GHTF Secretary for inclusion in the agenda of the fifth Steering Committee Meeting.

2.3.9 Following a request from Members during the third Meeting, Mr Dix provided a background, summary report on the pilot Global Vigilance Exchange System which has now concluded. A copy of this report was included among the agenda papers.

2.3.10 Members noted the report and considered a suggestion about making it publicly available via the GHTF website. In noting its usefulness for the Steering Committee discussion, some Members raised various concerns with certain sections of the report.

2.3.11 For example, while providing useful information, Members agreed the data presented in the table on page 3 could easily be misinterpreted by less informed readers. Further, certain references to 'confidentiality' would more than likely be misinterpreted by some stakeholder groups. Mr Dix clarified the report had been written with the knowledge that it was for distribution to Steering Committee Members only.

2.3.12 Members thanked Mr Dix for his report and agreed it contained a range of useful information which would be desirable to make publicly available. To address the previous concerns about misinterpretation, Members asked Mr Dix to re-write the report in a manner which would be suitable for public release and to provide a draft for consideration at the next Meeting.

Action:

The SG2 Chair to re-write the "Report on the SG2 Medical Device National Competent Authority Exchange Program - Pilot Phase" in a manner which would be suitable for posting on the GHTF website and forward the re-written draft to the GHTF Secretary for inclusion in the agenda of the fifth Steering Committee Meeting.

ITEM 2.4: UPDATE - STUDY GROUP 2 WORK PLAN

2.4.1 At the third Meeting, the Steering Committee noted the current and completed work items for SG2, but raised a number of further queries in relation to the proposed Postmarket Surveillance (PMS) project. Members agreed there was value in the proposed project, but prior to giving its endorsement to proceed, requested the SG2 Chair to more clearly define the work item and provide an updated proposal for further consideration at the fourth meeting.

2.4.2 The SG2 Chair, Mr Kim Dix drew Member's attention to the updated SG2 Work Plan (effective 1 March 2002) included among the agenda papers. The Plan includes timelines for all current work items and outlines a clearer definition for the proposed PMS project.

2.4.3 In discussing the updated Work Plan, Members outlined some additional comments and suggestions for SG2's further consideration including -

- The focus of the PMS project could be further 'sharpened' eg. the "Rationale for the Work" includes reference to 'gaining a new indication for a device'. Members noted this is more of a Study Group 1 matter and suggested the work de-emphasises issues relating to new applications and product effectiveness, and remains focused on market surveillance activities;

- Another important point requiring emphasis is that the majority of medical devices do not have extensive pre-market clinical data. Generally, the first clinical data is attained in the postmarket setting. Members noted this is a substantial topic in itself which can be further refined;

- A progress report on this project be the subject of a Workshop at the 10th GHTF Conference. The Committee agreed with this suggestion and indicated the Workshop should ideally involve the wider stakeholder group, including academic experts who could further assist with exploring existing methodologies which may be relevant to this project;

- As some products have relatively short life spans on the market, any progress on market surveillance studies for medical devices should progress on a globally harmonised basis (as opposed to being undertaken individually by national authorities); and

- It is also important to note the PMS project links into some of the work of Study Group 3.

2.4.4 Members agreed the proposal does not need to be further revised at this stage, as these issues would be best considered once SG2 commences work on the project. Members also noted some overlap of the project with the work of SG1 and SG3 and when appropriate, encourages SG2 to work in consultation with these Study Groups. The Steering Committee therefore gave approval for work to commence on the PMS project and subsequently endorsed the updated SG2 Work Plan (effective 1 March 2002).

Action:

1. As the program for the 10th GHTF Conference is being developed, the SG2 Chair to liaise with the incoming GHTF Secretariat to schedule a Workshop addressing SG2's 'progress to date' on its Postmarket Surveillance (PMS) project.
2. GHTF Secretary to present the four GHTF Study Group Work Plans in a standard format and post them on the GHTF website as agreed during the second and third Meetings (references - Steering Committee 2nd and 3rd Meeting Minutes, paragraphs 5.6.5 and 5.1.1.3 respectively).

ITEM 2.5: CONSIDERATION OF TWO STUDY GROUP 2 DOCUMENTS (N31 AND N33) AS "PROPOSED DOCUMENTS"

2.5.1 At the third Meeting, the Steering Committee gave consideration to a request from SG2 that the following documents be advanced to "Proposed Document" status -

1. Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices by a Manufacturer or its Authorized Representative; and

2. Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports.

2.5.2 Members expressed strong reservations at the suggestion of advancing draft guidance documents to "Proposed Document" status in the absence of a consensus position from the authoring Study Group. The Committee asked SG2 to undertake further work on the documents and requested that revised versions be submitted for further consideration during the fourth Steering Committee Meeting.

2.5.3 The SG2 Chair, Mr Kim Dix reiterated his earlier advice (from March 2002) that the Study Group has now convened a further meeting and come to the consensus that both documents should be posted for public comment as "Proposed Documents". In doing so, SG2 seeks to clarify any weaknesses and better identify the needs of the users of the documents.

2.5.4 In noting the outstanding concerns by some Members (in particular, strong objections by MHLW Japan to the inclusion of specific reporting dates), the SG2 Chair confirmed the documents are not intended to be considered final, nor ready for implementation at the end of the comment period. Rather, SG2 anticipates comments received will facilitate further refinement of the Proposed Documents.

2.5.5 While noting the objections by MHLW Japan, the GHTF Steering Committee agreed that the SG2 documents, N31R7.2 and N33R10 (as included among the agenda papers) be added to the GHTF website as a "Proposed Documents". The Steering Committee also agreed that N31R7.2 be posted for a six month comment period and N33R10 be posted for a three month comment period.

Action:

GHTF Secretary to post the SG2 documents, "Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices by a Manufacturer or its Authorized Representative (N31R7.2)" and "Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (N33R10)" to the GHTF website as "Proposed Documents".

2.5.6 Subsequent to the above agreement, the SG2 Chair returned to the Meeting the following day to advise Members that Section 6.0 ("Harmonisation Statement") in N33R10 had been moved and added (verbatim) to Section 1.0 ("Introduction") of the document following a request by an SG2 Member. Mr Dix confirmed there were no content changes to the document and no objections were raised by the Steering Committee to this minor, editorial amendment.

Action:

The SG2 Chair to forward the latest version of N33R10 to the GHTF Secretary for addition to the GHTF website as a Proposed Document.

ITEM 2.6: CONSIDERATION OF FOUR STUDY GROUP 2 DOCUMENTS (N6, N20, N32 AND N36) AS "FINAL DOCUMENTS"

2.6.1 The SG2 Chair advised the Steering Committee that the Document, "Comparison of the Device Adverse Event Reporting Systems in USA, Europe, Canada, Australia and Japan - N6R2" was approved as a "Final Document" during the 7th GHTF Conference and R2 is the version currently posted on the GHTF website.

2.6.2 Members noted this "Final Document" has since been updated, but the latest version, N6R3, dated 28 August 2000 (which was included among the agenda papers) is yet to be posted on the GHTF website. Mr Dix advised R3 is somewhat outdated at this point in time, but is more accurate than R2; and therefore sought the Steering Committee's approval to add version R3 to the website in place of the older version of the document.

2.6.3 Some Members expressed concern about posting a "Final Document" which contains known inaccuracies. Mr Dix advised the document was used as a reference tool in the development of N21 and since this work item has been finalised, there is no intention to continuously update N6. Nonetheless, N6R3 is the latest version developed and SG2 believes it is appropriate to post the document for historical purposes and to reflect the full amount of work undertaken at the time.

2.6.4 The Steering Committee agreed to post the SG2 document, N6R3 on the GHTF website as a "Final Document" (as a replacement to R2), along with a statement on the website page that - "this document contains outdated information and readers are advised to consult with the Founding Member government websites to obtain the latest regulatory requirements".

Action:

GHTF Secretary to post the SG2 document, "Comparison of the Device Adverse Event Reporting Systems in USA, Europe, Canada, Australia and Japan (N6R3)" on the GHTF website as a "Final Document", remove the document N6R2 and add a statement that "this document (R3) contains outdated information and readers are advised to consult with the Founding Member government websites to obtain the latest regulatory requirements".

2.6.5 The SG2 Chair advised the Steering Committee the following documents (which were included among the agenda papers) are currently on the GHTF website as "Proposed Documents" and sought Members' consideration of approving each as a "Final Document" -

1. Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria (N20R10);
2. Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3); and
3. Medical Devices: Post Market Surveillance: Manufacturers' Trend Reporting of Adverse Events (N36R4).

2.6.6 Mr Dix advised these documents have been posted on the GHTF website for public comment for an extended period of time. No comments have been received by SG2 on N20 or N36. Members also noted N32 is a guidance on format (not structure) and only one set of comments was received by SG2, which were considered in the final version. At its last meeting, SG2 considered all three documents final and ready for global national implementation.

2.6.7 Further written comments on these three documents were provided by a USA industry Member immediately prior the commencement of the Meeting. These comments were taken into account during the Committee's consideration of the three SG2 documents.

2.6.8 Most Members were prepared to endorse N20R10, although a further comment period was requested by USA industry. Part of the industry concerns revolved around the yet to be considered SG2 document, N38 ie. only a partial picture is currently available.

2.6.9 As the document had already been available for comment for approximately 12 months, there was majority agreement that it now be endorsed as a "Final Document". However, the Committee acknowledged that all "Final Documents" may be subject to amendment and therefore agreed that N20R10 be subject to further review in conjunction with the finalisation of N38, when that document becomes available for consideration.

Action:

GHTF Secretary to post the SG2 document, "Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria (N20R10)" on the GHTF website as a "Final Document".

2.6.10 With regard to N32R3 and N36R4, the Meeting was advised that additional concerns from USA and European industry have arisen since the last SG2 Meeting. As such, there is no longer consensus in the Study Group with regard to these documents. Efforts were made to resolve the outstanding concerns with N32 during the concurrent SG2 Meeting in Singapore, but these efforts were unsuccessful.

2.6.11 The Steering Committee subsequently agreed that these documents would not be approved as "Final Documents" and asked SG2 to review them in line with the current concerns raised by industry Members. Following this review, the SG2 Chair was asked to forward the revised versions of the documents to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

2.6.12 On a procedural point, the Steering Committee reaffirmed that where a Study Group was asking the Committee to approve a guidance document, it was important that a consensus position had already been achieved (and maintained) in the Study Group. In cases where a consensus cannot be achieved, the Study Group is encouraged to seek the Steering Committee's guidance on points of principle or any intractable issues.

Action:

Study Group 2 to review the documents, "Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3)" and "Medical Devices: Post Market Surveillance: Manufacturers' Trend Reporting of Adverse Events (N36R4)", in line with the current concerns raised by industry Members and forward revised versions of the documents to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

ITEM 2.7: APPOINTMENT OF CONFORMITY ASSESSMENT BODY REPRESENTATIVES TO THE GHTF STUDY GROUPS - PROPOSED AMENDMENT TO GHTF PROCEDURAL DOCUMENT, *"GHTF ROLES AND RESPONSIBILITIES"*

2.7.1 At the third Meeting, the Steering Committee agreed to amend paragraph 10.2 of the "*GHTF Roles and Responsibilities"* procedural document to clarify that representatives from conformity assessment bodies (CAB) may be appointed to the GHTF Study Groups by either regulatory authorities or industry associations.

2.7.2 This issue arose following a request from a Study Group Chair to be able to retain an individual from a CAB who was nominated by an industry association. Members recognised that some CAB representatives may possess specific expertise which is important for a Study Group's work program and agreed these representatives would be appointed on this basis and not as a representative of the nominating regulatory authorities or industry association.

2.7.3 Following circulation of the draft Minutes from the third Meeting, concerns with the above agreement were raised by some European industry Members. In view of those further concerns, the Chair decided not to proceed with the action item and include the matter for further discussion and resolution at the fourth meeting.

2.7.4 Members recalled the GHTF agreement when the three procedural documents were first adopted, that they would not be reviewed or amended until after the first three years of operation. One Study Group Chair noted it would be unwise to appoint an 'expert' if other Members of the Study Group had objections to that individual's participation. There was agreement that the GHTF Members should welcome the appointment of subject matter specialists with relevant expertise to the Study Groups, providing there was no conflicting interests with that appointment.

2.7.5 Members also noted the individual at the centre of this matter need not be excluded from the Study Group due to the aforementioned paragraph 10.2, since paragraph 6.5 of the *"GHTF Operating Procedures"* document states, in part -

"Study Group Chairs may, at their discretion, permit individuals who are not members of their Study Group or the GHTF to participate in their meetings, either as observers or technical experts. Similarly, they may also restrict participation in meeting discussions in order to ensure the purposeful conduct of business".

2.7.6 Following the above discussion, the Steering Committee agreed to rescind its previous decision to amend paragraph 10.2 of the "*GHTF Roles and Responsibilities"* procedural document.

ITEM 3: GHTF WEBSITE MANAGEMENT

3.1 The Secretary advised this item was presented to provide Members' with an opportunity to raise any issues or suggestions they have with regard to the on-going maintenance of the GHTF website; and drew Members' attention to a recent print-out of the "What's New" page which highlighted all recent additions/amendments to the site.

3.2 At the second Meeting, the Committee agreed that the Secretary include statistical information concerning the number of 'hits' to the GHTF website in future Meeting agendas. The Meeting noted the statistical information which was included among the agenda papers for the period, 1 September 2001 - 31 March 2002.

3.3 The Secretary then drew the Meeting's attention to the GHTF Strategic Review which has considered mechanisms by which to enhance communication of the GHTF and its activities. Members noted the GHTF website currently includes hyperlinks to the Founding Member government websites and 'other government sites'.

3.4 Members were advised that some of the peak industry associations from the Founding Member countries have now also established their own websites; and the Committee agreed that hyperlinks to these websites also be added to the GHTF website.

Action:

GHTF Secretary to include hyperlinks on the GHTF website to the Founding Member industry association websites.

3.5 Following publication of the 9th GHTF Conference Brochure, the GHTF Chair/Secretariat received a number of suggestions that use of the modernised GHTF logo (as presented in the Brochure) be expanded. It was proposed that this logo (and colour scheme) now replace the current version used on the GHTF website, letterhead, envelopes, etc. As the new logo includes yellow, concern was raised it may present poorly on white backgrounds and the Steering Committee therefore decided to retain the existing logo and colour scheme for the GHTF website, etc.

ITEM 4: REGIONAL HARMONISATION GROUP UPDATES

ITEM 4.1: ASIAN HARMONISATION WORKING PARTY

4.1.1 At the first Meeting, the Steering Committee agreed it was useful to receive updates from the regional groups and to retain these as 'standing items' for future meeting agendas.

4.1.2 A report from Dr Clarence Tan, Chair of the Asian Harmonisation Working Party (AHWP) and Chief Executive Officer, Singapore's Health Sciences Authority (HSA), outlining an overview of the AHWP's recent activities (which have occurred since the third Meeting) was included among the agenda papers.

4.1.3 Mr Wong Yew Sin (Director - Centre for Medical Device Regulation, HSA) was welcomed to the Meeting on Dr Tan's behalf. Mr Wong highlighted a recent survey of regulators in the Asian Member Economies, seeking information about their efforts to harmonise national medical device regulations with the GHTF's principles and recommendations. A copy of the survey questionnaire was included among the agenda papers.

4.1.4 Following the collation of survey results (received from 9 respondents out of a possible 10), Mr Wong advised that 68% of the Asian Member Economies are interested in considering the adoption and implementation of GHTF principles and recommendations. Only one country failed to respond to the survey as they are currently considering whether or not to establish a medical device regulatory framework.

4.1.5 Mr Wong also advised that 6 economies already have some form of medical device regulations implemented and 2 others (Singapore and Malaysia) are currently in the process of promulgating further regulations.

4.1.6 Members thanked Mr Wong for his report and agreed that the level of commitment being demonstrated by the Asian economies to embrace GHTF principles and guidance documents, and to enhancing their knowledge was impressive. The Steering Committee is supportive of these initiatives and welcomes the AHWP's focus and commitment as a regional group which is impressively lead by Dr Tan.

ITEM 4.2: AMERICAS WORKING GROUP

4.2.1 Mr Antonio Hernandez, Regional Advisor of the Pan American Health Organisation (PAHO) was welcomed to the Meeting and on behalf of PAHO and its Member States, thanked the Chair for the opportunity to address the Steering Committee.

4.2.2 Mr Hernandez explained that PAHO is the health organisation for the region of the Americas and is a regional office of the World Health Organisation. 2002 signifies PAHO's 100th year of operation. PAHO represents a broad spectrum of large and small economies, comprising 33 countries and 10 territories.

4.2.3 Many of the countries have insufficient human and financial resources, but respective governments are very clear of the need to protect their countries' populations. Medical device regulation is therefore a priority and PAHO is collaborating with its Member countries to assist with promulgating appropriate regulations.

4.2.4 Mr Hernandez advised the PAHO Member countries are committed to adopting a harmonised approach to regulation, based on GHTF principles. This commitment is demonstrated by the attendance of regulators from seven Latin American countries at the 9th GHTF Conference. Further, PAHO has sought to promote the GHTF through various events, academia and private sector industry associations.

4.2.5 Immediately following the 8th GHTF Conference in September 2000, the 42nd PAHO Directing Council passed a number of resolutions concerning medical device regulation, including a resolution to "promote and support the participation of regulatory authorities at general meetings of the GHTF, while promoting the use of GHTF documents in their programs for the regulation of medical devices". A full copy of the Resolution was included in the 9th GHTF Conference Binder.

4.2.6 Following this resolution, a number of significant achievements have been made in the Americas region, with the support and leadership of PAHO. These include -

1. Publication of the documents, "A Guide for the Development of Medical Device Regulations" and "A Model Regulatory Program for Medical Devices: An International Guide" (which were developed with the support of the US FDA and Health Canada). These documents are available in hardcopy and from the PAHO website - www.paho.org ;

2. With the support of the FDA and Brazilian regulatory authority, ANVISA, a VHS video of a recent medical device conference (which included promotion of the GHTF) has been produced and is now available from PAHO;

3. In 2001, a plan was finalised to host 5 medical device regulatory workshops over the next few years. The first Workshop has already been held in Colombia (and a report entitled, "International Workshop on the Regulation of Medical Devices - Andean Region" is now available). The second and third workshops are scheduled for later in 2002 and 2003; and

4. A Colombian Working Group has now translated the majority of GHTF Final Documents into Spanish. The Steering Committee agreed with a request from Mr Hernandez that these translated documents be added to the GHTF website. Members also noted that work on translating the documents into Portugese is soon to be undertaken by a Brazilian Working Group. When updating the GHTF website, Members also agreed that a hyperlink be established with the PAHO website.

Action:

GHTF Secretary to add the Spanish language versions of the GHTF Final Documents to the GHTF website and establish a hyperlink with the PAHO website - www.paho.org

4.2.7 Mr Hernandez provided copies of the above information (in various media) to the GHTF Secretary. He reaffirmed that the GHTF will continue to be a very important forum for Latin American countries, that PAHO will continue its work in this area and extended particular thanks to the US FDA and Health Canada for their on-going support.

4.2.8 The Chair thanked Mr Hernandez and the Steering Committee commended the significant efforts and achievements which have been made by PAHO and its Member Economies with the development of medical device regulatory systems and the commitment to adopt GHTF principles.

4.2.9 In concluding, Mr Hernandez asked if the Steering Committee could consider whether it will be possible to waive the registration fees for Latin American and Caribbean regulators wishing to attend the 10th GHTF Conference. Due to the financial situations in many of these countries, it is becoming increasingly difficult for regulatory representatives to participate in international fora such as the GHTF, despite a strong interest and commitment to do so. The Chair advised this request would be added to the agenda of the fifth Steering Committee meeting for consideration.

Action:

GHTF Secretary to include the following issue in the agenda of the fifth Steering Committee Meeting - "Consideration of waiving GHTF Conference Registration Fees for representatives of Latin American and Caribbean regulatory authorities".

ITEM 5: GHTF STUDY GROUP MATTERS

ITEM 5.1: UPDATE - STUDY GROUP 3

5.1.1 The Acting Chair of Study Group 3 (SG3), Dr Victor Dorman-Smith was welcomed to the Meeting. Members were advised there were no specific SG3 matters included in the agenda for consideration, but Dr Dorman-Smith advised some issues had arisen during SG3's concurrent meeting in Singapore.

5.1.2 The Meeting was advised the approved SG3 Work Plan includes the item, "Quality Planning for the Medical Industry". Recent amendments to ISO 13485 have significantly improved the requirements for 'quality planning' and SG3 believes the requirements are sufficiently explicit to negate the need for SG3 to develop its own guidance document on this subject. SG3 therefore recommends this item be deleted from its Work Plan.

5.1.3 The SG3 Work Plan also includes the item, "Risk Management Document". SG3 has become aware that a joint Working Group comprising representatives from ISO TC210 and the IEC has commenced work on a very similar item. SG3 therefore recommends that its commencement of work on this item be deferred until the product of the ISO/IEC Working Group becomes available for consideration.

5.1.4 [Secretary's note: Immediately following the Singapore meetings, the SG3 Chair, Ms Kimberly Trautman contacted the ISO/IEC Working Group Chair, Alf Dolan and delegate Harvey Rudolf concerning the Quality System and Risk Management Guidance Document. The Working Group does not have such a guidance document in their work plan and has no immediate plans for drafting such a document. The last ISO/IEC meeting minutes were not clear on this decision. Ms Trautman, in consultation with Dr Dorman-Smith and Mr Dolan then agreed that SG3 should proceed with the original work plan item with two members of the ISO/IEC Working Group invited to participate in this effort. A small group will commence drafting the guidance during August - September 2002 and the document will be further progressed by SG3 during a meeting scheduled for February 2003].

5.1.5 In considering the draft international standard, ISO 13485, SG3 considers some issues (including the requirements on risk management) are not well expressed. SG3 has undertaken to provide comments to ISO TC210 to assist with clarifying these issues.

5.1.6 SG3 has also reconsidered the Final Document, "Process Validation Guidance for Medical Device Manufacturers" which was approved three years ago. The requirements for process validation in the current international standard are now significantly different to those in the Final SG3 document. In order to update the document, SG3 recommends this item be added to its current Work Plan.

5.1.7 Members thanked Dr Dorman-Smith for his comprehensive report and approved the recommended changes to the SG3 Work Plan.

Action:

The Study Group 3 Chair (or Acting Chair) to update the SG3 Work Plan to reflect the changes approved by the Steering Committee and forward the revised plan to the GHTF Secretary for addition to the GHTF website.

5.1.8 *All current Matters for Study Groups 1, 2 and 4 are "matters arising from previous meetings" and have been included at Item 2 of the agenda.*

ITEM 6: DRAFT GHTF STRATEGIC PLAN: 2002-2007

6.1 At the third Meeting, the Steering Committee decided the first draft of the Plan needed to be re-drafted in order to present a more 'outcome oriented' document and agreed that the re-drafting be done in terms of identifying the "Vision", "Mission", "Goals" and "Actions" with specified "Timeframes".

6.2 Members agreed that the re-drafting be undertaken by a small drafting committee and the product of the drafting team's effort was e-mailed to Members on 5 April 2002 and was also included among the agenda papers (6th Draft, dated 4 April 2002).

6.3 The Vice-Chair re-introduced the subject and circulated an updated version of the Draft Plan (7th Draft, dated May 2002) which further minor enhancements. Members were advised the document currently does not include 'delivery dates' against the "Actions" listed under each "Goal" in the Plan.

6.4 As per the program for the 9th GHTF Conference, Members were reminded that a 'near final' version of the document would be presented during the Plenary Session on 15 May 2002. Members were therefore asked to advise if they were supportive of the content of the document, as presented.

6.5 Following further discussion and consideration of concerns raised by some Members, there was general agreement with the overall content of the document. However, the Steering Committee agreed that the following amendments be made to the document prior to presentation (of the 8th Draft) at the Conference's Plenary Session and subsequent addition to the GHTF website -

- As the 'Plan' is yet to be finalised, the document be retitled as, "GHTF Strategic Directions: 2002 - 2007";
- The "Vision" statement be amended to read, "enhancing the health of the public worldwide and facilitating innovation by harmonising the global regulatory environment";
- The "Mission" statement be omitted;
- Use of the term, "Actions" be omitted and replaced with, "Tasks";
- The first sentence of Goal 1 be amended to, "the GHTF will encourage and support the timely identification and introduction of significant new medical technologies **and emerging risks**";
- Goal 3 be amended to, "the GHTF will **seek to** evolve beyond convergence….";
- Goal 3, Tasks 1 and 2 be amended to the following three tasks -

  i "GHTF Members will agree to accept common data mutually";
  ii "GHTF Members will encourage acceptance of common data amongst other national/regional authorities"; and
  iii "GHTF Members will encourage the uptake of the approved "STED" and other common technical documents amongst other national/regional authorities; and
- Goal 6 be amended to, "GHTF Members will **seek to** establish an affordable….".

6.6 Following acceptance of the "Goals" (as amended), Members also agreed that a statement to the following effect be included as a foreword in the document -

'The Tasks included in this document provide more explanation of each Goal, but at this stage, no firm commitment can be given to achieving all the Tasks by any specified dates until there is further investigation of factors such as the resources required, competing priorities, etc'.

6.7 Members also agreed the document be included in the agenda for the next Meeting, in order to determine how to achieve/implement each of the identified Tasks within specified timeframes.

Action:

1. The GHTF Vice-Chair to amend the Draft Strategic Directions document in line with Members comments outlined above and present the revised Document (8th Draft) during the GHTF plenary on 15 May 2002;
2. Following the 9th Conference, the GHTF Secretary to add the document to the GHTF website when all other conference presentations are being added; and
3. GHTF Secretary to include the Draft GHTF Strategic Directions document in the agenda of the fifth Steering Committee Meeting for further consideration of achieving/implementing the identified Tasks within specified timeframes.

ITEM 7: GHTF TRAINING

7.1 At the third Meeting, Members made numerous comments and suggestions with regard to the possible development of a program or policy relating to GHTF training (including the handling of any formal requests for training).

7.2 The Steering Committee agreed with a suggestion that Mr Brekelmans and Mr Gropp prepare a framework for a draft procedural document addressing the future conduct of GHTF Training, for consideration at the fourth Meeting. A copy of the draft document was included among the agenda papers.

7.3 Members were advised, that when developing the paper, the authors took the view that GHTF-related training may take two forms -

1. "GHTF training", which would be offered under the auspices of, and with the authority of the GHTF (following approval by the Steering Committee); and

2. "Training on GHTF", which provides general information and raises awareness of the GHTF, its activities, etc. This training would normally be part of national programs, commercial events, etc and are not subject to Steering Committee approval.

7.4 The paper outlined further details relating to these two forms of training and provided guidance on how such training may be structured and delivered (through to Section 6.0). Members then considered and agreed with Section 7.0 of the paper which proposed to establish a new section in the "General Information" page of the GHTF website. This section would be used to list forthcoming GHTF-related training events, agendas and presentations.

7.5 The paper concluded with Section 8.0, which addressed a proposed "GHTF Training Institute" (an issue which has been the subject of prior discussions by the Committee). Mr Gropp suggested that any such Institute is best addressed in the context of the proposed GHTF Permanent Secretariat. Members endorsed this view and agreed that Section 8.0 be removed from the current document (and be the subject of a separate paper for further consideration at the next meeting).

7.6 Members suggested several other minor amendments to the paper and there was general agreement that the paper be adopted as a reference guide for the Steering Committee and added to the GHTF website. Prior to finalising the document, Members agreed to forward any further comments to Mr Gropp within 30 days and a revised version would be circulated to Members for endorsement out-of-session.

Action:

1. Following the receipt of any further comments by Members, Mr Brekelmans and Mr Gropp to update the Discussion Paper on GHTF Training and forward the revised version to the GHTF Secretary.
2. GHTF Secretary to distribute the document to all Members via e-mail for final comment and endorsement.
3. Once the paper is endorsed, GHTF Secretary to create a new 'GHTF training' section in the "General Information" page of the GHTF website and add the final version of the Discussion Document, in addition to information on any future training events, as the information becomes available.
4. Mr Brekelmans and Mr Gropp to prepare a Discussion Paper addressing the possible establishment of a GHTF Training Institute (for consideration in conjunction with the proposal to establish a GHTF Permanent Secretariat), and forward the paper to the GHTF Secretary for inclusion in the next meeting agenda.

ITEM 8: ESTABLISHMENT OF A PERMANENT SECRETARIAT

8.1 At the third Meeting, the Steering Committee considered several options for a GHTF Secretariat, including a Permanent Distributed Location ie. a network/global model. The Meeting was advised this option would involve each 'regulatory' Founding Member designating one staff member to become part of a global secretariat network with defined responsibilities.

8.2 There was general support from a majority of Members to further investigate the feasibility of this option and the Committee agreed with a suggestion that the current GHTF Secretary, in consultation with the two, former GHTF Secretaries from Health Canada and the US FDA ("the GHTF Secretaries"), refine the proposal for further discussion at the next Meeting.

8.3 The Secretary advised that in addition to investigating the feasibility of this option, the GHTF Secretaries also gave consideration to four further options which in part, were based on current and previous discussions of the Steering Committee. The five options investigated were -

1. Permanent Distributed Location;
2. Regionally Rotating Secretariat;
3. Regulator and Industry Shared Secretariat;
4. Continually Rotating Secretariat (the current model); and
5. Permanent Single Location.

8.4 The GHTF Secretaries' document was included among the agenda papers and Members noted the 'pros' and 'cons' of each option which were outlined for consideration. The paper then detailed an options analysis, whereby each option was rated against nine criteria, using a three point scale (comprising "yes", "somewhat" and "no").

8.5 Members also noted the GHTF Secretaries' recommendation that the Steering Committee move towards adopting and implementing Option 5 within the next two years and maintains the current model (Option 4) in the interim period. In making this recommendation, the GHTF Secretaries noted this model is consistent with the approach adopted by other major, international organisations eg. ICH, APEC and PIC/S.

8.6 Further, the commitment to fund this option should not be seen as an insurmountable obstacle. After all, under the current model (Option 4), each of the Founding Member regulatory authorities already make a significant financial and resource contribution to the operation of the GHTF Secretariat.

8.7 However, prior to implementing this option (if accepted), the Secretary advised a more detailed feasibility assessment would be required to address a number of 'policy', 'funding' and 'logistical' issues, including secretariat location, sources of funding, budgets, appropriate staffing levels, etc.

8.8 In summarising all Members' views, the Chair noted majority support for further investigation of Option 5. The Chair also noted some Members' reservations with this option and requests for more detailed consideration prior to the Committee being asked to make a final decision.

8.9 The Committee subsequently agreed to establish a Working Group to further investigate the feasibility of establishing a single permanent location for the GHTF Secretariat. Members noted there will be several permanent models to consider and a range of key issues to be resolved, including the hosting or location, governance, staffing and funding.

8.10 The Committee agreed that the membership of the Working Group would be - Mr Gropp (Chair), Mr Britain, Dr Gill, Mr Brekelmans, Mr Gerard, Dr Rotter, Mr Matsumoto, Mr Isobe, Mr Davies, Ms Jocelyn Kula (former Secretary, Health Canada) and Mr Robert Eccleston (former Secretary, US FDA). Members agreed that the Working Group will report back to a future Steering Committee meeting.

Action:

The Permanent Secretariat Working Group (chaired by Mr Gropp) to further investigate the feasibility of establishing a single permanent location for the GHTF Secretariat and report its findings to a future Steering Committee meeting for further consideration.

ITEM 9: COLLABORATION BETWEEN THE GHTF AND WORLD HEALTH ORGANISATION (WHO)

ITEM 9.1: WHO PARTICIPATION IN GHTF STEERING COMMITTEE AND STUDY GROUP MEETINGS

9.1.1 A Member asked the Steering Committee to consider a proposal to grant observer status to the WHO to allow the organisation's participation in meetings of the GHTF Steering Committee and Study Groups. The Committee was advised this proposal follows a request from the WHO to a European industry association (and Steering Committee Member).

9.1.2 Members acknowledged the important role played by the WHO, particularly with respect to countries with developing regulatory systems. Further, the Committee agreed it would be undesirable for another peak, global organisation to be developing its own guidance on the regulation of medical devices in isolation of GHTF activities.

9.1.3 The Committee also reaffirmed its willingness to work constructively with other organisations and noted paragraphs 6.1 and 12.0 of the procedural document, *"Roles and Responsibilities"*. These Sections of the document outline in some details, the GHTF's ability and commitment to establish working relationships with other organisations.

9.1.4 However, paragraph 6.1 also specifies the structure of the Steering Committee and only specifies that "observers and advisers from the Founding Members may also attend Steering Committee meetings". With regard to observers participating in Study Group Meetings, Members also noted that paragraph 6.5 of the *"GHTF Operating Procedures"* document states, in part -

"Study Group Chairs may, at their discretion, permit individuals who are not members of their Study Group or the GHTF to participate in their meetings, either as observers or technical experts.

9.1.5 As previously discussed during the Meeting, Members recalled the GHTF agreement that the three procedural documents will not be reviewed or amended until after the first three years of operation. In view of this agreement, Members accepted there is currently no scope to grant observer status to the WHO to allow the organisation to participate in full meetings of the Steering Committee.

ITEM 9.2: WHO DRAFT *"GUIDELINES FOR THE DEVELOPMENT OF MEDICAL DEVICE REGULATIONS"*

9.2.1 At the third Meeting, Members were advised the WHO had commenced work on a document entitled, *"Guidelines for the Development of Medical Device Regulations"*. The Guidelines have been well received by WHO Member States in the Americas region, but are mainly restricted to the Canadian and USA regulatory systems.

9.2.2 The WHO advised the Guidelines are now being expanded to include the Australian, Japanese and European regulatory schemes in order to make them relevant for global use. Members expressed their support for this WHO initiative and agreed to provide the necessary information to assist the further development of the Guidelines.

9.2.3 Following the third Meeting, some Members provided comments on the Draft Guideline which were forwarded to the WHO for consideration. The latest draft received from the WHO was subsequently e-mailed to Members on 23 April 2002. The Meeting noted the WHO was keen to receive further comments from GHTF Members and has raised the possibility of issuing the Guideline as a joint WHO/GHTF document when finalised.

9.2.4 While remaining supportive of WHO initiatives, particularly those aimed at assisting countries with developing regulatory systems, Members were concerned with the WHO proposal of issuing a joint document. To become formally involved with the Guideline would require a significant resource contribution.

9.2.5 The Committee also noted the extensive amount of resources already invested by GHTF Members during the past 10 years, in addition to current and future resource commitments. This investment has lead to the development of a suite of world's best practice, harmonised guidance documents, which are already publicly available on the GHTF website. The Steering Committee commends the Final Documents to all participants of the global community (from both, developed and developing countries) with an interest in the regulation of medical devices.

9.2.6 The Committee was pleased to have assisted the WHO by providing comment on the Draft Guidelines up to this point, but no Member was in a position to commit any additional time and resources for further, on-going reviews of the Guidelines. The Committee also noted its further support of this WHO initiative, by including the Guidelines in the program of the 9th GHTF Conference as a Workshop Session.

ITEM 9.3: PROPOSED MEMORANDUM OF UNDERSTANDING BETWEEN THE GHTF AND WHO

9.3.1 At the third Meeting, Members noted the WHO would like to develop joint activities with the GHTF and its Study Groups to unify international regulatory requirements for medical devices. To facilitate this, the WHO's Mr Gerald Verollet suggested that a Memorandum of Understanding (MoU) or other appropriate document be developed in order to formalise the collaboration.

9.3.2 The Committee extended its 'in-principle' support to the development of an MoU between the GHTF and WHO. On 21 November 2001, the Chair extended an invitation to Mr Verollet to prepare a draft outline of the major elements which would comprise such an agreement, for consideration during the fourth Meeting.

9.3.3 The document was not available for inclusion among the agenda papers, although a preliminary framework was provided by Mr Verollet on 25 April 2002 and tabled during the Meeting.

9.3.4 In further discussing this matter, the Committee considered the document would require significant revision before being suitable for adoption. Further, some Members raised concerns that, with initiating the request to develop an MoU, the it appears the WHO's own procedural mechanisms had not been followed.

9.3.5 The Meeting was advised that the mechanism to establish an MoU between the WHO and another organisation normally commences with a resolution issued by the World Health Assembly (WHA). Such resolutions provide the mandate to proceed and are generally signed by the WHA's Director-General.

9.3.6 Further, any document which is entitled, "Memorandum of Understanding" has a very specific meaning and ramifications for certain jurisdictions. Any draft document would require detailed technical and legal scrutiny by GHTF Members before an agreement could be formally established.

9.3.7 Members reaffirmed their 'in-principle' support to the development of an MoU between the GHTF and WHO, but agreed the matter would not receive further consideration until a formal request (or resolution) was received via the correct lines of authority in the WHO.

9.3.8 Following the preceding discussions (including those at Items 9.1 and 9.2), Mr Verollet was welcomed to the Meeting following an invitation from the Chair. Mr Verollet outlined his major interests in working with the GHTF, including -

- possible participation by the WHO in meetings of the Steering Committee and Study Groups;
- the safety and vigilance requirements for medical devices;
- the possibility of further progressing the draft *"Guidelines for the Development of Medical Device Regulations"*; and
- that these issues could possibly be further elaborated upon and advanced via the development of an MoU between the WHO and GHTF.

9.3.9 The Chair thanked Mr Verollet for addressing the Meeting and advised the Committee had already discussed most of the issues he raised. Ms Maclachlan advised the discussions would be summarised in the Minutes of the Meeting and that she would also write to Mr Verollet to further address some of the issues raised.

9.3.10 With specific regard to the possible development of an MoU, the Chair advised Mr Verollet of the procedural concerns outlined above and advised him of the Committee's decision that the matter will not receive further consideration until a formal request (or resolution) was received via the correct lines of authority in the WHO.

Action:

1. The Chair to write to the WHO's Mr Gerald Verollet, as a follow-up to the preceding discussions concerning any on-going collaboration between the GHTF and World Health Organisation.
2. In order to pursue the establishment of a Memorandum of Understanding with the GHTF, Mr Gerald Verollet to arrange for the GHTF Chair to receive a formal request (or resolution) from the correct lines of authority within the WHO.

ITEM 10: REGULATION OF MEDICAL DEVICES CONTAINING HUMAN TISSUES

10.1 A European industry Member asked the Steering Committee to consider a proposal to develop an internationally harmonised approach to the regulation of medical devices containing human tissues.

10.2 The Meeting was advised that GHTF Members are currently working on the development of their own regulations to address this particular issue and it was suggested that it is easier to achieve harmonization before having national regulations in place. To commence discussions now at the Steering Committee level will indicate a very strong commitment from GHTF members ie. GHTF will be seen to be taking the right decision at the right time. To react only when national regulations are in place will illustrate a lost opportunity. It was suggested that a Working Group be established to develop a detailed proposal for further consideration.

10.3 In the discussion that followed, Members noted a diversity of views and that all five jurisdictions are at different stages of reviewing the regulatory processes for human tissue products. Members were advised of the proposed revision to Japan's Pharmaceutical Affairs Laws and that Australia is in the process of making a number of recommendations to the respective Health Ministers. Members were also advised that a new 'Biologics' Directorate has been established in Health Canada and currently, legal advice is being sought to clarify the lines of responsibility between the regulation of biological products and medical devices.

10.4 The FDA (CDRH) is not likely to regulate a large number of human tissue products as medical devices. There will however, be a few categories of 'biological medical devices'. A public hearing is scheduled for June 2002 and the outcomes will assist the FDA in making its decision on how to proceed with the regulation of these products.

10.5 In Europe, a guideline (jointly developed by the UK MDA, Medicines Control Agency, industry and academia) is currently available on the MDA's website. "Third Wave" or "Hybrid" legislation which treats tissue products separately to pharmaceutical products and medical devices is currently subject to parliamentary consideration in Europe. This process will move more quickly than GHTF and at the same time, precludes European regulatory participation in any GHTF Working Group.

10.6 Members noted that a clearer picture is more likely to have emerged in all jurisdictions by the time of the next Steering Committee meeting. It was therefore suggested the issue be included in the agenda of the next Meeting, in order to further consider how the current processes have developed and to avoid possible duplication of effort.

10.7 As certain political processes are moving quickly, the Committee decided not to establish a Working Group at this point in time. The Steering Committee regulators agreed to provide written reports for the next meeting, outlining the current status of the regulation of these products in their jurisdictions. Following consideration of these reports, the Steering Committee would then be in a better position to determine how the issue of harmonising the regulatory approaches to medical devices containing human tissues may be best progressed.

Action:

1. The Steering Committee regulators to prepare written reports from their jurisdictions outlining progress to date on the regulatory approaches to medical devices containing human tissues.
2. The Steering Committee regulators to forward their reports to the GHTF Secretary for inclusion in the agenda of the fifth Meeting.

ITEM 11: EUCOMED GLOBAL STANDARDS STRATEGY DISCUSSION DOCUMENT

11.1 The Meeting was advised the Chair had received a letter from Dr Trudy Phelps (Hon Secretary of the EUCOMED Standards Focus Group and Standards Director of the Association of British Healthcare Industries, ABHI) requesting the Steering Committee give consideration to EUCOMED's Global Standards Strategy Discussion Document, *"Improving International and European Healthcare Standardisation to meet Global Safety, Regulatory and Market Needs"*. A copy of the Discussion Document was included among the agenda papers.

11.2 It was proposed the Steering Committee discuss the need for some type of global strategic healthcare standards group to agree on key strategies, objectives and priorities for both international and European healthcare standardisation from a global perspective.

11.3 Members were advised that at present, there is no joint ISO/CEN group or any other group that effectively addresses this need. EUCOMED's paper outlines some of the issues currently being observed and suggests some potential benefits of establishing such a group (including a possible scope, membership, potential issues that might be addressed, etc).

11.4 However, no proposals have been made as to the best 'location' of such a group (eg. whether within the GHTF, within ISO/CEN, or within an existing umbrella standards committee such as ISO/TC 210, all of which are possibilities).

11.5 The Chair invited all Members to comment on the EUCOMED proposal and a summary of the major points or common issues is outlined below -

- Duplication of effort in the standards development area needs to be addressed and this is an important point from a public health perspective;
- Regulatory systems are increasingly embracing international standards;
- Participation in various standards' committees is a large and on-going resource commitment;
- Since having the authority to permit manufacturers to cite standards without supporting evidence (since 1997), the CDRH has now established a core group to evaluate relevant standards. Internet searches have identified approximately 600 standards which are relevant to medical devices and a random sample of 510K applications revealed more than half cited standards as part of the product application process; and
- Harmonisation and standardisation operate together, but it is important that the safeguarding of public health remains the first priority. It was noted, that in some circumstances, standards are developed with different mandates and 'people interests'.

11.6 Members acknowledged this is an important area for further work and welcomed EUCOMED bringing it to the Steering Committee for consideration. As work has already commenced at the European level, it was suggested this could be expanded to a global level. Members noted, that with its international membership, the GHTF possesses the ability to diffuse problems associated with duplication of effort.

11.7 In supporting the EUCOMED proposals, the Committee agreed to establish a Working Group to further examine the exact type of input the GHTF could offer the process. It was also agreed this Working Group would be chaired by Mr Gerard and he would establish the Group from within the Steering Committee membership.

Action:

Mr Roland Gerard to canvass Steering Committee Members to participate in the Global Standards Strategy Working Group and forward a report to the GHTF Secretary for inclusion in the next Meeting agenda, which outlines a proposal for further GHTF involvement in a global strategic healthcare standards group.

ITEM 12: MEDICAL DEVICE REGULATORY RESPONSES TO BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)

12.1 A USA industry Member requested the Steering Committee have an informal discussion on the regulatory approaches and responses in each jurisdiction to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

12.2 Members noted the reports from each of the five GHTF Founding Member regulators, in particular, those from the TGA, European Commission and MHLW Japan, which were included among the agenda papers.

12.3 An industry Member raised the concern that each time a new BSE/TSE risk emerged, industry were faced with different approaches being adopted by different governments. Members were asked to consider whether the Steering Committee could assist with harmonising these approaches by developing a single standard or guidance document.

12.4 The regulatory Members agreed this issue evoked strong views and while all Founding Member regulators adopt risk averse approaches, these approaches are often different due to political responses falling outside the regulatory arena.

12.5 Members applauded the idea of a harmonised approach to the BSE/TSE issue, but flagged caution as to how far the GHTF could progress the issue when considering its limited expertise in the area (compared to other organisations), that the impact of BSE/TSE extends far wider than medical devices and the fact this issue will always inevitably involve a political response or reaction. Further, a harmonised approach to BSE/TSE issues may be difficult to achieve given its significantly different status across the GHTF's three geographic regions.

12.6 The Committee asked the industry Member to further consider the suggestion of developing a BSE/TSE guidance document in view of the current discussions. If the Member considers there are still outstanding issues which fall within the Steering Committee's purview, the Committee agreed that the Member prepare a paper for further consideration at the next Meeting.

Action:

Mr Gerard to prepare a paper outlining any BSE/TSE issues which fall with the Steering Committee's purview and forward the paper to the GHTF Secretary for inclusion in the agenda for the next Meeting.

ITEM 13: OTHER BUSINESS/LATE PAPERS

ITEM 13.1: REGISTRATION FEES FOR GHTF CONFERENCES

13.1.1 In a letter dated 4 March 2002, the GHTF Chair advised of the decision to maintain a differential in the registration fees for government and non-government delegates attending the 9th GHTF Conference, following extensive consultation with all Members. The differential allowed government delegates to pay a lower fee than other delegates.

13.1.2 Some industry members disagreed with the fee differential, whereas the government members agreed with the proposal, which is consistent with the well established practice now adopted for most national and international conferences. Further, during the second Meeting in Brussels, the Steering Committee endorsed the principle of a fee differential when it agreed to government regulators attending the 9th Global Medical Devices Conference in Barcelona at a discounted rate.

13.1.3 However, the government members were generally sympathetic to the industry concerns and have acknowledged this was a precedent for GHTF Conferences. In view of this, the Chair decided to include the issue in the meeting agenda for further discussion. A summary of Members' comments is outlined below -

- European industry - a fee differential is not such a problem for major companies, but if the intention is to reach the industry at large (smaller companies included), it must be remembered that all do not have 'deep pockets';

- European regulators - a good compromise was achieved for the 9th Conference after all significant factors were considered. It is important to keep such issues in perspective since registration fees are virtually a negligible cost compared to airfares, accommodation and 'out of office' time. Finally, smaller regulatory agencies do not have 'deep pockets' either and the need to charge speakers and principle Members to attend their own Conference was questioned(*);

- USA industry - no strong feelings either way, providing the 'principle of equal partnership' is maintained, although differential registration fees would not undermine this principle. The more important issue is the success of GHTF work products and achieving the goals of harmonisation;

- USA regulator - no strong feelings either way. Differential registration fees would not 'make or break' the success (or otherwise) of a GHTF Conference;

- Canadian industry - need to consider objectives of hosting GHTF Conferences. If the GHTF wishes to target a large number of attendees, efforts must be made to minimise costs where possible;

- Japanese regulator - a good compromise was achieved for the 9th Conference. There is a need to accept shared responsibilities for hosting GHTF Conferences; and

- Australian industry - fees should be common, although Australian industry supported the compromise for the 9th GHTF Conference. In moving ahead, there is a need to maintain a clear demonstration of the government-industry partnership and all parties should strive to keep costs as low as possible.

(*) This was a precedent started at a previous GHTF Conference in the interests of ensuring the regulatory agency hosting the event achieved full cost recovery (or close to it). GHTF Steering Committee and Study Group Members need to pay Conference registration fees as collectively, they represent approximately 40% of the attendees.

13.1.4 The Committee agreed that all comments be noted in the Minutes, but in the absence of a consensus, no decision or outcome would be recorded with regard to the future setting of GHTF Conference registration fees.

Secretary's Note: The 9th GHTF Conference was attended by 219 delegates representing 29 countries, the largest GHTF gathering to date. 180 delegates attended the 2nd APEC Seminar on the Harmonisation of Medical Device Regulations (compared to 70 delegates who attended the first APEC Seminar held in March 2000).

ITEM 13.2: RETIREMENT OF MS BETH PIETERSON

13.2.1 On 19 February 2002, Ms Beth Pieterson tendered her resignation as a Member of the GHTF Steering Committee, advising Members she would be starting "new challenges in another area of Health Canada". Ms Pieterson was the Director of Health Canada's Medical Devices Bureau and the immediate past GHTF Chair.

13.2.2 Through her leadership, perspective and ability to find common ground, the Steering Committee acknowledged Ms Pieterson's chairmanship of the GHTF as a period of significant achievement and vision. Members expressed their appreciation to Ms Pieterson for making a significant contribution to the GHTF and international harmonisation, and extended their best wishes to her for the future.

ITEM 13.3: RETIREMENT OF MR MICHAEL BAKER

13.3.1 Mr Michael Baker, Director-General, EUCOMED retired with effect from May 2002. At the second Meeting, Members were advised of Mr Baker's retirement from the Steering Committee and recalled he was also a Member of the GHTF Ad Hoc Procedures Group, the predecessor to the Steering Committee.

13.3.2 The Steering Committee acknowledged Mr Baker's long-standing commitment to the GHTF and its objectives, and noted the pivotal role he played from the European industry perspective. Members expressed their appreciation to Mr Baker for his significant contribution to the GHTF and its global activities, and extended their best wishes to him for the future.

ITEM 13.4: RETIREMENT OF MR JAMES BENSON

13.4.1 Mr James (Jim) Benson, Executive Vice-President, Technology and Regulatory Affairs, AdvaMed has tendered his resignation from the Steering Committee in view of his impending retirement on 30 June 2002.

13.4.2 The Steering Committee acknowledged Mr Benson's strong commitment to the GHTF and its objectives. Members expressed their appreciation to Mr Benson for his significant contribution to the GHTF and its global activities, and extended their best wishes to him for the future.

Action:

USA industry to advise the GHTF Chair of their nomination of a new member to the Steering Committee, to fill the vacancy that will be created on 30 June 2002 by Mr James Benson's retirement.

ITEM 13.5: 10TH GHTF CONFERENCE

13.5.1 Further to the preliminary advice provided during the 2nd and 3rd Meetings, the Japanese Members of the Steering Committee distributed a brochure confirming that the 10th GHTF Conference would be held at the Toshi Center Hotel, Tokyo, Japan from Sunday, 25 - Wednesday, 28 May 2003. This Conference will be followed by the 10th Global Medical Devices Conference at the same venue on Thursday, 29 - Friday, 30 May 2003.

Action:

1. GHTF Secretary to add the dates and location for the 10th GHTF Conference to the "Conferences" page of the GHTF website.
2. In consultation with the incoming GHTF Chair, the incoming GHTF Secretariat to prepare a draft program for the 10th GHTF Conference and include this draft in the agenda of the fifth Meeting for consideration (in line with paragraphs 6.1 - 6.3 of the procedural document, *"GHTF Operating Procedures"*).

ITEM 14: TIMETABLE FOR FUTURE GHTF MEETINGS

14.1 The Chair advised the GHTF Chair and Secretariat are officially scheduled to rotate to the Ministry for Health, Labor and Welfare (MHLW), Japan on 1 July 2002. The transition of the Chair and Secretariat will commence during July 2002 and it is expected the rotation will be completed immediately after the fifth Steering Committee Meeting.

14.2 Mr Isobe drew Members' attention to the MHLW's suggestions that the 5th and 6th Steering Committee meetings be held in Tokyo during September 2002 and February 2003. Mr Isobe advised this proposed schedule was based on Paragraph 6.4 of the procedural document, *"GHTF Operating Procedures"* which specifies the Steering Committee will meet not less than two times between GHTF Conferences.

14.3 It was generally agreed there would be insufficient work items for the Steering Committee to consider at meetings in both, September 2002 and February 2003 (and again during the 10th GHTF Conference in May 2003). Members noted the requirement of the procedural document is based on the premise that GHTF Conferences are generally held every 18 months. Given the re-scheduling of the 9th Conference, there will only be 12 months between Conferences on this occasion.

14.4 In view of this, it was suggested the Steering Committee convene one further meeting before the 10th Conference, one in conjunction with, and one after the Conference (in the latter part of 2003). There was general agreement with this and Members subsequently agreed with a revised proposal from Mr Isobe that -

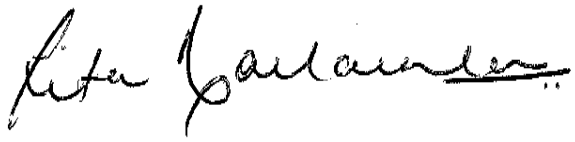
1. the 5th Steering Committee meeting (and first under Japan's chairmanship of the GHTF) be held in Tokyo from Monday, 28 - Wednesday, 30 October 2002; and

2. the 6th Steering Committee meeting be held in Tokyo in conjunction with the 10th GHTF Conference during May 2003.

14.5 The Chair thanked all participants for their attendance and contributions to the meeting's achievements, and looked forward to the remainder of the 9th GHTF Conference throughout the forthcoming week.

14.6 In noting this as the final Steering Committee meeting under her chairmanship, Ms Maclachlan extended her sincere thanks to all Members for their continuous support during the past 18 months. Ms Maclachlan advised she had enjoyed Australia's term as GHTF Chair and looked forward to a continuation of the Committee's productive working relationship. The Chair closed the meeting at 5.40pm.

Meeting record prepared by Mr Craig Davies, GHTF Secretary (Australia).



Rita Maclachlan
GHTF Chair; and
Director
Conformity Assessment Branch
Therapeutic Goods Administration

Craig A Davies
GHTF Secretary
Conformity Assessment Branch
Therapeutic Goods Administration

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