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 November and December 2001; and will be endorsed at the Committee's 4th Meeting on 12 -13 May 2002.

MINUTES

STEERING COMMITTEE - 3rd MEETING

ROOM 1211
HANNIBAL HOUSE
UK MEDICAL DEVICES AGENCY
ELEPHANT AND CASTLE
LONDON, UNITED KINGDOM

THURSDAY, 11 - FRIDAY, 12 OCTOBER 2001

AGENDA **PAGE NO.**

The 3rd Meeting of the Global Harmonisation Task Force (GHTF) Steering Committee was held in Room 1211 - Hannibal House at the UK Medical Devices Agency's headquarters, London, United Kingdom from Thursday, 11 - Friday, 12 October 2001.

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
Mr Barry Evers-Buckland - Medical Industry Association of Australia

Japan: Mr Masato Yoshida - The Japan Federation of Medical Devices Associations
Mr Kenichi Matsumoto- The Japan Federation of Medical Devices Associations

Canada: Ms Beth Pieterson - 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 James Benson - Advanced Medical Technology Association (*)
Mr Michael Gropp - Advanced Medical Technology Association

Europe: Mr Cornelis Brekelmans - European Commission
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
Dr Egid Hilz - COCIR
Dr Carl Wallroth - EUROM VI

Observers: Dr Taisuke Hojo - Ministry for Health, Labor and Welfare - Japan
Mr Daisuke Koga - Ministry for Health, Labor and Welfare - Japan

SG Chairs: Mr Maurice Freeman, Chair - GHTF Study Group 1
Mr Kim Dix, Chair - GHTF Study Group 2
Ms Kimberly Trautman, Chair - GHTF Study Group 3 (*)
Dr Horst Frankenberger - Interim Chair, GHTF Study Group 4

Secretary: Mr Craig Davies - Therapeutic Goods Administration

(*) These Members participated in the Meeting for approximately 3-4 hours each afternoon via a video conference link between London and Washington DC. The Chair commenced each afternoon's session by providing an overview of the morning session and inviting further comment or input from the USA Members on the issues previously discussed.

LIST OF ABBREVIATIONS

ADVAMED	Advanced Medical Technology Association
AHWP	Asian Harmonisation Working Party
CCAB	Centre Conference Albert Borchett
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
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
1.1 Welcome and Introduction GHTF Chair to respond to Lord Hunt, thanking him for his letter of support to the GHTF and its objectives.	Completed, 24/10/01
1.3: Conflict of Interest Members to note the Steering Committee's revised agreement regarding the handling of any 'conflict of interest' issues.	Referred to Members for noting, 13/11/2001
1.5: 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/action, 13/11/2001
Mr Rainer Voelksen to advise the GHTF Secretary of the new contact details for himself and the Swiss Federal Office of Public Health when the current organisational changes are completed.	Referred to Mr Voelksen, 13/11/01. Completed 16/1/02
2.1: Global Medical Devices Nomenclature (GMDN) Maintenance Agency Policy Group GHTF Steering Committee regulators to undertake an evaluation of the GMDN within their own jurisdictions and forward their reports to the GHTF Secretary for inclusion in the next meeting agenda.	Referred to regulator members, 13/11/2001
Mr Freeman and/or Mr Boyer to forward a report from the second meeting of the MAPG to the GHTF Secretary for inclusion in the next Steering Committee meeting agenda.	Referred to Mr Freeman/Mr Boyer, 13/11 & 3/12/2001
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)"* At its next meeting, GHTF Study Group 4 to address the issues raised by NEMA and amend the scope and introduction of '*Supplement No.4 - Compilation of Audit Documentation (Clause 5.7)'* to also clarify that the document is primarily intended to provide guidance to auditors and is not intended as a tool to facilitate the transfer of information between regulatory authorities.	Referred to SG4 Chair, 13/11/2001
After the next SG4 Meeting, the SG4 Interim Chair to forward the revised document to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG4 Chair, 13/11/2001
2.3: Implementation of the Global Vigilance Exchange System GHTF Study Group 2 to address the issues outlined above, refine its proposal on full implementation of the NCAR Exchange Program and the SG2 Chair to forward a revised proposal to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 13/11/2001
The SG2 Chair to prepare a background, summary report on the Global Vigilance Exchange pilot and forward the report to the GHTF Secretary for circulation to Members out-of-session.	Referred to SG2 Chair, 13/11/2001

2.4: Re-scheduling of the 9th GHTF Conference The GHTF Chair to respond to the RAPS Executive Director, thanking the organisation for its support of the GHTF, but declining the invitation to explore ways to link the RAPS and GHTF Conferences in Budapest during early May 2002.	Completed, 20/11/2001
The GHTF Chair, in conjunction with the Dr Clarence Tan investigate the possibility of hosting the 9th GHTF Conference and APEC sponsored training event in Singapore sometime during mid-April to mid-May 2002;	Completed, 22/10 - 2/11/01
Following these discussions, prepare a draft proposal for out-of-session consideration and/or endorsement by the Steering Committee.	Completed, 6/11/01
Once confirmed by the Steering Committee, the GHTF Chair and Secretary to proceed with publicising and arranging the events in conjunction with Dr Tan and AdvaMed.	In progress, December 2001/ January 2002
2.5: New Study Group 2 Chair The SG2 Chair to forward his biographical details to the GHTF Secretary for inclusion on the GHTF website.	Completed, 3/12/2001
3: GHTF Website Management GHTF Secretary to e-mail GHTF PowerPoint templates number 1 and 2 (as tabled during the Meeting) to Members for future use when preparing GHTF presentations.	Completed, 13/11/2001
4.1: Asian Harmonisation Working Party GHTF Chair to advise the AHWP Vice-Chair that the Steering Committee is supportive of the AHWP developing a website and agreed that an internet hyperlink be established with the GHTF website once the AHWP site is operational.	Completed, 3/12/2001 Websites linked, 24/1/2002
4.3: Report from the Sino-US Workshop on Quality System Regulation and ISO Requirements for Medical Devices, Kunming, China: 11-13 September 2001 GHTF Secretary to distribute the Kunming Workshop report to Members once the US Department of Commerce provides the final, approved version.	Completed, 3/12/2001
5.1.1: Update - Study Group 1 Work Plan Further to the second Meeting, GHTF Secretary to present the Study Group Work Plans in the standard format agreed upon and post them on the GHTF website once the four Plans are endorsed by the Steering Committee.	In progress, January 2002
5.1.2: Review and Approval of the SG 1 Document, *"Medical Devices Classification"* as a "Final Document" When completed, the SG1 Chair to forward the document, *"Medical Devices Classification"* to the GHTF Secretary for inclusion in the agenda of the 4th Steering Committee meeting.	Referred to SG1 Chair, 13/11/2001
5.1.3: Study Group 1 Membership The Study Group 1 Chair to review and amend the current SG1 membership list in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of the Group's Members represent).	Referred to SG1 Chair, 13/11/2001

5.2.1: Update - Study Group 2 Work Plan The SG2 Chair to forward a revised Work Plan to the GHTF Secretary in the format presented for Study Group 1, for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 13/11/2001
The SG2 Chair to more clearly define the proposed Postmarket Surveillance project in line with Members comments and forward an updated proposal to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 13/11/2001
5.2.3: Consideration of Study Group 2 Documents GHTF Secretary to post the SG2 document, *"Global Medical Devices Competent Authority Report (N9R10)"* to the GHTF website as a "Final Document" in place of the existing version (R5).	Completed, 14/11/2001
GHTF Secretary to post the SG2 document, *"Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3)"* to the GHTF website as a "Proposed Document".	Completed, 14/11/2001
GHTF Secretary to amend the document header to indicate the correct revision number, "R3".	Completed, 14/11/2001
Members to provide further comments on the SG2 document, *"Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices (N31R6)"*, to the SG2 Chair by 31 December 2001 (copying their comments to all other Members for information); and	Referred to Members, 13/11/2001
SG2 to review the document in line with the Committee's consideration and additional comments received; and forward a revised version to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 13/11/2001
Members to provide further comments on the SG2 document, *"Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (N33R9)"*, to the SG2 Chair by 31 December 2001 (copying their comments to all other Members for information); and	Referred to Members, 13/11/2001
SG2 to review the document in line with the Committee's consideration and additional comments received; and forward a revised version to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.	Referred to SG2 Chair, 13/11/2001
5.3.1: Proposed Merger of SG3 and SG4 GHTF Chair to write to all SG3 and SG4 Members advising of the Committee's decisions with regard to the future direction and structure of the two Study Groups.	Completed, 22/11/01
5.3.2: Study Group 3 Membership GHTF Secretary to prepare a draft amendment to Paragraph 10.2 of the "*GHTF Roles and Responsibilities"* procedural document, to clarify that CAB representatives may be appointed to Study Groups by either regulatory agencies or industry associations for their specific expertise (but not as a representative of the nominating organisation).	Not progressed. To be referred to 4th Meeting for further consideration
GHTF Secretary to circulate the draft amendment to Members for comment and once endorsed by the Steering Committee, incorporate the amendment into the final procedural document currently posted on the GHTF website.	" "

5.3.3: Possible Removal of ISO 13488 from the list of TC 210 Quality Management System Standards The SG3 Chair to forward a summary from the SG3/TC210 Meeting held in Barcelona from 13 October 2001 to the GHTF Secretary for circulation to Members. Steering Committee Members to provide written comments to the GHTF Chair on the ISO proposal concerning the possible removal of ISO 13488 from the list of TC 210 Quality Management System Standards.	Superseded/completed, 7/11/01 - SG3 Chair advised "TC210 went ahead and decided to eliminate ISO 13488 and collapse it into ISO 13485 in a similar manner as ISO 9001:2000".
5.4.1: Study Group 4 Membership JFMDA and MEDEC to advise the Interim SG4 Chair and GHTF Chair/Secretary when their new nominations to the SG4 Membership have been finalised.	Referred to Members from JFMDA & MEDEC, 13/11/01
The Interim SG4 Chair to review and amend the SG4 membership list in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of the Group's Members represent).	Referred to Interim SG4 Chair, 13/11/2001
6.1: Draft GHTF Strategic Plan: 2002-2006 The Vice-Chair to convene a preliminary meeting with the TGA to progress the draft Strategic Plan (in the manner agreed by the Committee); and subsequently liaise with the remaining Members of the drafting committee in order to prepare an updated draft Plan for consideration and/or endorsement at the next Meeting.	Referred to Vice-Chair, 13/11/01; Meeting held 21-22/11/01. Further draft prepared, progress continuing, January 2002
6.2: Draft Guidelines - Regulatory Requirements for New and Emerging Technologies GHTF Secretary to include the issue, *"Regulatory Requirements for New and Emerging Technologies"* in the agenda of the 9th GHTF Conference's Plenary Session as a "Special Topic" item.	For noting by GHTF Secretary
7: GHTF Training Mr Brekelmans and Mr Gropp to prepare a framework for a draft procedural document addressing the future conduct of GHTF Training and forward the 'framework' to the GHTF Secretary for inclusion in the next meeting agenda.	Referred to Mr Brekelmans & Mr Gropp, 13/11/2001
8: Establishment of a Permanent Secretariat The GHTF Secretary to liaise with the two, former GHTF Secretaries from Health Canada and the US FDA, to further consider and refine the proposal to establish a global secretariat network for the GHTF; and prepare a paper for inclusion in the next Meeting agenda.	In progress, January 2002
10.1: Proposed Collaboration between the GHTF and World Health Organisation (WHO) The GHTF Chair to respond to the WHO's letter dated 10 October 2001 advising of the Steering Committee's consideration of the WHO project, *"Harmonisation on the Regulation of Medical Devices"* and the suggested approach to progressing the issues and suggestions raised.	Letter from Chair forwarded to WHO inviting draft outline for an MoU, 21/11/2001
10.2: Retirement of Dr Egid Hilz European 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 31 December 2001 by Dr Egid Hilz's retirement.	Referred to COCIR & European industry Members, 13 & 20/11/2001. Completed, new member appointed, 15/1/2002

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 and the GHTF Study Group Chairs to London, United Kingdom for the third meeting of the GHTF Steering Committee. Ms Maclachlan expressed her thanks and appreciation on behalf of the Committee to Dr David Jefferys for his invitation to host the meeting and for making the necessary arrangements.

1.1.2 In particular, the Chair welcomed new Member, Dr Carl Wallroth (representing EUROM VI) to his first Steering Committee Meeting and also Mr Kim Dix from Health Canada, in his capacity as the new Chair of GHTF Study Group 2.

1.1.3 Dr Taisuke Hojo and Mr Daisuke Koga (Ministry for Health, Labor and Welfare - Japan) were also welcomed to the Meeting as observers, in place of Mr Souichi Ikegaya and Mr Soichiro Isobe.

1.1.4 Apologies were received from -

- Mr Souichi Ikegaya - Ministry for Health, Labor and Welfare - Japan;
- Mr Soichiro Isobe - Ministry for Health, Labor and Welfare - Japan;
- Mr Dennis Baker - United States Food and Drug Administration;
- Mr Hanz-George Will - Federal Department for Health, Germany; and
- Mr Roland Gerard - EUCOMED.

1.1.5 Ms Maclachlan indicated how pleased she was that it was possible to convene this meeting at such short notice following the postponement of the 9th GHTF and Global Medical Devices Conferences in Barcelona, due to the tragic events of 11 September 2001 in the USA. The Chair advised those Members present that the USA based Members would be participating in the meeting each afternoon via a video conference link between London and Washington DC.

1.1.6 The Chair tabled a letter dated 11 October 2001 from Lord Hunt of Kings Heath, the UK Parliamentary Under Secretary of State, Department of Health. Lord Hunt's letter offered the UK Government's support to the GHTF and Members were honoured to note this support of the GHTF's objectives in furthering public health and safety through a harmonised regulatory scheme for medical devices.

Action:

GHTF Chair to respond to Lord Hunt on behalf of the Steering Committee, thanking him for his letter of support to the GHTF and its objectives.

ITEM 1.2: ADOPTION OF AGENDA

1.2.1 Members accepted and adopted the items presented in the agenda for this meeting and agreed that the following additional items be added to the agenda for discussion -

- consideration of a standard PowerPoint template for Members' use when preparing future 'GHTF presentations', to be raised under Item 3 - GHTF Website Management;

- advice of GHTF participation in recent training programs in Kuala Lumpur, Malaysia and Kunming, China to be raised under Item 4 - Regional Harmonisation Group Updates (Items 4.1 and 4.3 respectively); and
- a letter from the World Health Organisation (WHO) proposing a closer linkage between the GHTF and WHO, to be raised under Item 10.1 - Other Business/Late Papers.

ITEM 1.3: CONFLICT OF INTEREST

1.3.1 At the second Meeting, Members agreed that 'conflict of interest' be added as a standing item at the beginning of each subsequent meeting agenda. The Meeting noted this provides the opportunity for the Chair to ask Members to identify any perceived or direct 'conflicts' they may have in relation to any agenda item; and subsequently allow the full Committee (less the potentially affected member/s) to address any issues on a case-by-case basis (prior to the commencement of the Meeting proper).

1.3.2 The Chair suggested this issue be re-visited and asked for Members' advice as to whether 'conflict of interest' was really required as a standing item for all meetings. The Meeting noted the Steering Committee does not give consideration to issues concerning individual products and that industry Members have been appointed to represent the broad interests of their respective associations, not individual companies.

1.3.3 The Steering Committee agreed to rescind its earlier agreement. However, the Committee subsequently agreed that if an issue ever arose that a company may benefit from (by virtue of an employee's membership on the Committee), then, in the interests of transparency and due process, it would be the expectation of the Committee that the Member declare the interest (or potential interest) prior to the Committee's deliberation of the particular issue.

Action:

Members to note the Steering Committee's revised agreement with regard to the handling of any 'conflict of interest' issues.

ITEM 1.4: MINUTES FROM THE 2nd STEERING COMMITTEE MEETING

1.4.1 The Minutes from the 2nd Steering Committee Meeting were included in the agenda papers and incorporated all comments received on the draft Minutes that were circulated on 12 July 2001.

1.4.2 Members were reminded the Minutes had been posted on the GHTF website on 6 September 2001. There were no further comments and the Minutes were subsequently ratified by the Committee as a true record.

ITEM 1.5: GHTF STEERING COMMITTEE MEMBERSHIP LIST AND CONTACT DETAILS

1.5.1 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.

1.5.2 The Meeting was advised of organisational changes currently occurring within the Swiss Federal Office of Public Health. Mr Voelksen advised he would inform Members of the changes and new contact details when the process was completed.

Action:

1. Members to review the Steering Committee Membership List and advise any changes to the GHTF Secretary.
2. Mr Rainer Voelksen to advise the GHTF Secretary of the new contact details for himself and the Swiss Federal Office of Public Health when the current organisational changes are completed.

ITEM 2: MATTERS ARISING FROM PREVIOUS MEETINGS

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

2.1.1 At the second Meeting, Members considered the GHTF should support the Global Medical Devices Nomenclature (GMDN) and noted that achieving consistency in areas such as nomenclature is fundamental to the overall goal of international harmonisation.

2.1.2 While remaining supportive of the initiative, some industry Members recognised (and raised some concerns) relating to the use, costs and benefits of the GMDN within their organisations. Industry Members were asked to provide feedback on these issues for consideration during the third meeting. During the third Meeting, industry Members advised they subsequently decided not to further consider these issues until a better understanding of how regulatory agencies would use the GMDN was obtained.

2.1.3 Industry Members also advised they would support the GMDN, but only for future activities, not retrospectively. The Meeting also noted there would be a need to monitor cost issues associated with its implementation and use; and that the GMDN is essentially a regulatory tool for use at the industry/regulatory interface ie. the nomenclature would have limited use within the industry itself and is not considered to be a relevant consumer issue.

2.1.4 Industry Members sought further clarification concerning use of the GMDN in regulatory practices and whether its use would be voluntary or mandatory. There was general agreement among the regulatory Members that the GMDN would be used for pre-market and post-market activities. With regard to the latter point, Members agreed the GHTF could not apply either a 'voluntary' or 'mandatory' status to the GMDN as this would be an issue of sovereignty for individual countries to determine.

2.1.5 Following the second Meeting, Health Canada's, Mr Don Boyer (Manager of the Device Licensing Services Division within the Medical Devices Bureau) accepted an invitation from the Chair to be the GHTF representative on the GMDN Maintenance Agency Policy Group (MAPG). Mr Boyer attended its first full meeting on 19-20 July 2001 in London and a copy of his report was included among the agenda papers.

2.1.6 Members noted that the GHTF Study Group 1 Chair, Mr Maurice Freeman, had been appointed as Chair of the MAPG. Mr Freeman also provided the Committee with a detailed (verbal) report on the major issues discussed during the first MAPG meeting.

2.1.7 The Meeting was advised the MAPG comprises 14 Members (with four regulators from the European Commission, USFDA, MHLW and GHTF, and five Members each representing the interests of ISO and CEN).

2.1.8 The Meeting was also advised the GMDN currently comprises 18,000 terms and the immediate work for the MAPG is to organise its updating and implement a system which allows for the creation of regular updates. It is being proposed that copies of the 'update package' will be available for sale to manufacturers on a twice yearly basis at a price determined by the MAPG.

2.1.9 Funding is currently a sensitive issue. While some believe the GMDN should be freely available, reality is that a source of funding is required to provide the update service and resource a secretariat. While remaining supportive of the concept, some industry Members advised their organisations would not be prepared to make a financial commitment until they have a full understanding of how the system will be implemented and subsequently used.

2.1.10 The Meeting was advised cost issues require further consideration by the MAPG, but a very preliminary estimate of 1,500 EURO once or twice per year, to receive updates of the nomenclature had been flagged. The Meeting was also advised there has been considerable interest in the GMDN from the procurement and health services areas; and that these may be potential sources of revenue.

2.1.11 The Meeting noted the GMDN copyright is currently held by CEN who were mandated by the European Commission to develop the initial nomenclature. CEN has now delegated the operation/administration of the copyright provision to the MAPG.

2.1.12 In addition to the MAPG now receiving requests for copies of the GMDN from around the world, the Meeting was advised that the US FDA is currently evaluating the GMDN to determine whether it can be adopted within its regulatory framework and that the MHLW has commenced the major exercise of translating the nomenclature into the Japanese language.

2.1.13 On 10 October 2001, a meeting was held at the US FDA to consider progress with the organisation's evaluation of the GMDN. The Meeting noted the FDA is pleased with the progress being made by the MAPG, but has some concerns with the overall cost of the program and some of the nomenclature being considered. The FDA may consider using their current nomenclature system and the GMDN side-by-side for a transitional period.

2.1.14 The Meeting also noted some regulatory authorities are currently evaluating the GMDN and that others are already keen to implement the nomenclature within their regulatory frameworks. 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 next meeting.

Action:

GHTF Steering Committee regulators to undertake an evaluation of the GMDN within their own jurisdictions and forward their reports to the GHTF Secretary for inclusion in the next meeting agenda.

2.1.15 Members agreed that these evaluations must be undertaken in partnership with the medical devices industry, in a non-burdensome manner. Industry Members advised they would support the adoption of the GMDN in a prospective (but not retrospective) manner within the scope of pre-market and post-market regulatory activities.

2.1.16 The Committee noted the latest reports provided on the GMDN and the first meeting of the MAPG; and endorsed the following recommendations -

1. "The GHTF encourages all participating regulatory agencies to evaluate the GMDN as quickly and as thoroughly as possible. The success of the GMDN as an 'international' product for regulatory purposes is contingent upon acceptance by the regulatory agencies of the GHTF"; and
2. "The GHTF continues to support the GMDN as an important product for the exchange of regulatory information between industry and regulators, and between regulatory agencies. Although too early to tell, the acceptance of an 'international' nomenclature system would greatly assist with other harmonization activities currently under development within GHTF".

2.1.17 Members were advised the second meeting of the MAPG will be held during mid-October 2001 and requested that a report be provided for further discussion at the next Meeting.

Action:

Mr Freeman and/or Mr Boyer to forward a report from the second meeting of the MAPG to the GHTF Secretary for inclusion in the next Steering Committee meeting agenda.

2.1.18 The Steering Committee reaffirmed its earlier view that the GMDN will be a major contribution to international harmonisation among regulatory agencies, particularly in vigilance and the worldwide registration of products.

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 second Meeting, the Steering Committee agreed not to approve '*Supplement No.4 - Compilation of Audit Documentation (Clause 5.7)'* as a "Final Document".

2.2.2 Members asked that the USA industry concerns (which related to the large amount of information required to be retained by manufacturers, the ease of 'transferability' of this volume of information, confidentiality and the requirement that auditors' hand written notes be documented and archived), be provided in writing to enable further consideration by Study Group 4 (SG4).

2.2.3 A copy of NEMA's letter to the SG4 Interim Chair was included among the agenda papers. The Meeting was advised, that following the postponement of the Study Group meetings scheduled for mid-October 2001 in Barcelona, it was now likely that SG4 would convene its next meeting sometime during early 2002.

2.2.4 In addition to NEMA's letter, the Chair sought further input from Members during the Meeting. The SG4 Interim Chair also asked whether Members believed that auditors' working documents/hand written comments should be exchanged between regulatory agencies.

2.2.5 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. Members requested that SG4 amend the scope and introduction of the document to address this, and the other issues raised by NEMA, and present the revised document to the next Meeting for further consideration.

Action:

1. At its next meeting, GHTF Study Group 4 to address the issues raised by NEMA and amend the scope and introduction of '*Supplement No.4 - Compilation of Audit Documentation (Clause 5.7)'* to also clarify that the document is primarily intended to provide guidance to auditors and is not intended as a tool to facilitate the transfer of information between regulatory authorities.
2. After the next SG4 Meeting, the SG4 Interim Chair to forward the revised document to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

ITEM 2.3: IMPLEMENTATION OF THE GLOBAL VIGILANCE EXCHANGE SYSTEM

2.3.1 At the second Meeting, the Steering Committee regulators agreed the pilot 'vigilance exchange' scheme had been highly beneficial from a public health and safety perspective and gave 'in-principle' support to proceed towards full implementation of the scheme.

2.3.2 Prior to achieving this, the Committee agreed that it needed to consider a formal proposal from SG2 on this matter which addresses all relevant issues, including the following -

- the need for SG2 to undertake an evaluation of the pilot;
- the criteria upon which full implementation of the system will be based;
- confidentiality; and
- how to educate 'new users' of the system ie. those NCA's who have not been involved in the pilot scheme.

2.3.3 The proposal developed by Study Group 2 (SG2) was included among the agenda papers at Item 5.2.3, Paper G. The SG2 Chair outlined the following summary of the requirements considered by SG2 for participation in a National Competent Authority Report (NCAR) Exchange Program. Participants would need to -

i) have a functioning adverse event reporting system;
ii) agree to confidentiality requirements;
iii) agree to the adoption of finalised SG2 documents;
iv) participate in an appropriate training program (to be developed);
v) have an identified designated contact point;
vi) agree to participate in exchange of reports and provide feedback if requested; and
vii) provide the status of any agreements or obligations that might require the country to supply information that would be in a NCAR.

2.3.4 In view of recent comments received by SG2 that the term, 'vigilance report' may be a source of confusion in some countries, the Meeting noted that SG2 had developed the new term, *National Competent Authority Report* (NCAR).

2.3.5 Members raised a number of issues, including those relating to the full scope of the proposal, the various sources of incident reports ie. users as well as manufacturers), confidentiality of incident reports, how to ensure the most appropriate information is released at the most appropriate time, criteria for accepting new participants into the scheme and training for these new participants.

2.3.6 With regard to confidentiality, some Members asked what mechanisms would be established to ensure manufacturers' reports retained a degree of confidentiality in a global exchange network. Following discussion, there was general agreement that the safeguarding of public health was the key priority/objective and not 'confidentiality' *per se*. Given the structure of the European Union, the European regulators clarified that the larger countries who ultimately participate in the NCAR Exchange Program would be required to forward adverse event reports to the smaller European countries in the interests of public health.

2.3.7 Further, the Meeting noted that adverse event reports could not be kept confidential in view of the requirements of *Freedom of Information* legislation in various countries. In considering that 'confidentiality' was not the major issue, Members strongly believed that the release of the wrong or inappropriate information by one participant at the wrong time was the more important factor to address.

2.3.8 Members agreed it would be critical to ensure there were appropriate safeguards and training programs set in place to ensure that misleading information or information that could cause undue concern across global communities would not be released under any new system. For example, it was noted that one adverse event whose report is subsequently exchanged worldwide needs to be seen and considered in the appropriate context.

2.3.9 Additionally, Members also noted the need for a mechanism (perhaps incorporated as part of the training programs) to ensure that recipient countries handle the adverse event reports in an appropriate manner and do not initiate undue regulatory action (or inaction) within their own jurisdictions.

2.3.10 Some Members also questioned the need for 'providing feedback', as referred to in point 6 above and under the heading, "GHTF partnership/participant" on page 3 of the proposal presented among the agenda papers. It was considered this could place an unnecessary obligation and workload upon recipient countries and the benefit of this to NCA's was questioned.

2.3.11 Concern was also raised as to whether any country that was able to meet criteria 1-7 above would have to be automatically accepted into the program. Members agreed the proposal needs to clarify the definition of "participating members" or "participating countries".

2.3.12 It was also suggested that the Steering Committee be the body that decides who the participants in any future program will be. While not objecting to the proposal, some Members flagged that any such decision-making would need to be undertaken with great sensitivity to ensure there was no perception that the countries represented on the Steering Committee could be seen as passing judgement on the adequacy (or otherwise) of other countries' adverse event reporting systems. It was agreed to discuss this issue in more detail once a revised proposal is prepared by SG2.

2.3.13 Given the complexity and range of issues outlined above, the question of how the system would be fully implemented was also raised. Members agreed with a suggestion that SG2 also gives consideration to whether it would be possible to implement the system via a two staged process eg. whether Stage 1 could constitute another type of 'pilot' scheme which would ultimately lead to Stage 2, being the full implementation.

2.3.14 The Steering Committee agreed that the draft document presented among the agenda papers at Item 5.2.3, Paper G represented a 'blueprint' for a NCAR Exchange Program, but agreed that the issues raised above need to be further addressed before full implementation of the system can proceed.

Action:

GHTF Study Group 2 to address the issues outlined by the Committee, refine its proposal on full implementation of the NCAR Exchange Program and the SG2 Chair to forward a revised proposal to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

2.3.15 To assist with the on-going consideration of this issue, the SG2 Chair agreed with a request from Members to provide a background, summary report on the pilot Global Vigilance Exchange System which has now concluded.

Action:

The SG2 Chair to prepare a background, summary report on the Global Vigilance Exchange pilot and forward the report to the GHTF Secretary for circulation to Members out-of-session.

ITEM 2.4: RE-SCHEDULING OF THE 9TH GHTF CONFERENCE

2.4.1 Due to the postponement of the 9th GHTF Conference in Barcelona, the suggestions previously raised by Members for future GHTF Meetings are no longer feasible and the issue required new discussion during the third Meeting.

2.4.2 The Chair noted that the central issues for the Steering Committee to now decide upon are -

i) whether or not to re-schedule the 9th GHTF Conference; and
ii) whether or not to co-host the GHTF Conference with the re-scheduled 9th Global Medical Devices (GMD) Conference (if this eventuates); or
iii) to host the GHTF Conference as a 'stand alone' event.

2.4.3 The Chair advised she had maintained regular contact with Mr Michael Baker (Director-General, EUCOMED) following the postponement decision. The latest advice from Mr Baker was that there is a great deal of uncertainty with regard to whether the EUCOMED Board will decide to re-schedule the 9th GMD Conference.

2.4.4 Notwithstanding this uncertainty, the Steering Committee agreed there were numerous significant matters on the Barcelona conference program eg. the GHTF Strategic Plan, the regional group information sessions, GHTF Training, the GMDN, regulatory requirements for new and emerging technologies and other difficult regulatory issues facing government and industry alike. The Committee therefore agreed to re-schedule the 9th GHTF Conference.

2.4.5 In considering the amount of time required to organise an international event of this nature, in conjunction with Mr Baker's advice, the Committee also regrettably decided that the GHTF Conference should proceed as a 'stand alone' event and not be co-hosted with the re-scheduled 9th GMD Conference (if this eventuates).

2.4.6 The Chair also advised the Meeting of an APEC sponsored training proposal which has been developed by AdvaMed to provide training on the GHTF principles and guidance documents to industry representatives and regulators in the Asian region. The bid proposed that this training be hosted in either Singapore or Hong Kong.

2.4.7 Prior to the Meeting, the Chair and AdvaMed had held discussions on the proposal and how it may be associated with the re-scheduled GHTF Conference. During the most recent teleconference on 3 October 2001, AdvaMed advised their funding bid had been approved. It was agreed that it would be preferable for this event to proceed in either Singapore or Hong Kong as both cities are 'travel hubs', travel would be less expensive for many delegates and wider participation could therefore be anticipated. It was also agreed that it would be too difficult at this stage to re-locate the event to Australia, if Australia were to be considered a suitable venue for the re-scheduled Conference.

2.4.8 In the discussion that followed, it was noted the APEC training event would involve participation by some GHTF Members. In considering the costs associated with international travel and the overall poor feasibility of hosting two major (related) events in the Asia/Pacific region within a few months of each other, the Steering Committee agreed the best option would be to host the 9th GHTF Conference and the APEC sponsored training event 'back-to-back' in the same country.

2.4.9 In considering a suitable time, the Meeting was advised of a number of other relevant international events which had already been scheduled for the first half of 2002. One such event is the 2002 European RAPS Conference which has been scheduled for 6-9 May 2002 in Budapest, Hungary. The Chair advised Members of a letter from RAPS' Executive Director extending the organisation's support to the GHTF and an invitation to explore ways to link the RAPS and GHTF Conferences. Members noted these events and suggested that the 9th GHTF Conference and APEC training event be held sometime during mid-April to mid-May 2002, with all possible efforts being made to avoid a scheduling conflict with an event which has already been notified.

2.4.10 In considering a venue for the re-scheduled GHTF Conference, the Steering Committee agreed that Singapore was the preferred choice for a number of reasons -

i) the country is a 'travel hub' and is easier for Europeans and Americans to visit compared to Australia;
ii) Singapore would attract a larger number of Asian participants than Australia;
iii) there would be the ability to build even stronger linkages with the Asian Harmonisation Working Party (AHWP), whose Chairman, Dr Clarence Tan, is based in Singapore; and
iv) the country was one of the nominated venues for the APEC sponsored training event.

Action:

The GHTF Chair to respond to the RAPS Executive Director, thanking the organisation for its support of the GHTF, but declining the invitation to explore ways to link the RAPS and GHTF Conferences in Budapest during early May 2002.

2.4.11 The Committee agreed that the Chair, in conjunction with Dr Clarence Tan, proceed with investigating the possibility of hosting the 9th GHTF Conference and APEC sponsored training event in Singapore, as suggested above. Following these discussions, the Committee agreed that a draft proposal then be prepared for out-of-session consideration and/or endorsement by Members.

2.4.12 If it eventuated that Singapore was not a viable option, the Committee also agreed that the Chair then investigate either Australia or Hong Kong as possible venues.

Action:

1. The GHTF Chair, in conjunction with the Dr Clarence Tan investigate the possibility of hosting the 9th GHTF Conference and APEC sponsored training event in Singapore sometime during mid-April to mid-May 2002;
2. Following these discussions, prepare a draft proposal for out-of-session consideration and/or endorsement by the Steering Committee; and
3. Once confirmed by the Steering Committee, the GHTF Chair and Secretary to proceed with publicising and arranging the events in conjunction with Dr Tan and AdvaMed.

2.4.13 The Study Group Chairs then sought the Committee's views in relation to re-scheduling their postponed meetings. The Committee agreed that the four Study Groups would meet during the re-scheduled 9th GHTF Conference, but if the Chairs considered there was a need to meet before mid-April to mid-May 2002, then that was a matter for the Chairs to decide upon in conjunction with their Members.

ITEM 2.5: NEW STUDY GROUP 2 CHAIR

2.5.1 At the second Meeting, the Steering Committee agreed that the Chair formally invites Health Canada's Mr Kim Dix to accept the position of Study Group 2 (SG2) Chair, following Dr Larry Kessler's recent resignation from the position.

2.5.2 The Committee noted Mr Dix's correspondence dated 1 August 2001, accepting the invitation to assume the position of SG2 Chair. Mr Dix thanked the Committee for its earlier welcome and advised Members that he and Dr Kessler are still working through a transition period and it is their intention that Dr Kessler attends one final SG2 Meeting to finalise the hand over of responsibility.

Action:

The SG2 Chair to forward his biographical details to the GHTF Secretary for inclusion on the GHTF website.

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 June - 31 August 2001.

3.3 The Chair then drew the Meeting's attention to the issue of consistency with GHTF PowerPoint presentations which are continually being delivered by Members to various forums around the world. Instead of Members using their own corporate PowerPoint templates, it was suggested that two, GHTF PowerPoint templates be posted on the website for future use by Members.

3.4 Four proposed templates were e-mailed to Members on 5 October 2001 and colour copies were tabled during the Meeting, numbered 1 - 4. The Committee accepted the Chair's suggestion and selected templates 1 and 2 as the agreed GHTF PowerPoint templates. However, concern was raised with regard to posting the templates on the GHTF website which would allow access to all members of the public worldwide. The Committee agreed that templates 1 and 2 be e-mailed to Members and Study Group Chairs for retention in their own electronic filing systems.

Action:

GHTF Secretary to e-mail GHTF PowerPoint templates number 1 and 2 (as tabled during the Meeting) to Members for future use when preparing GHTF presentations.

3.5 Some Members asked whether it would be acceptable to add their own corporate logos to the templates. The Committee considered this request and agreed that individual corporate logos may be added to the GHTF PowerPoint templates at the discretion of individual Members.

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 The Steering Committee noted a report from Dr Clarence Tan, Chair of the Asian Harmonisation Working Party (AHWP), outlining an overview of the AHWP's recent activities (which have occurred since the second Meeting).

4.1.3 The Chair advised that she and other GHTF Members participated in the 1st Technical Committee Meeting and Workshop of the AHWP in Kuala Lumpur, Malaysia on 6-7 September 2001.

4.1.4 The event was attended by 56 delegates and those GHTF Members present agreed that the level of commitment being demonstrated by the Asian economies to embracing GHTF principles and to enhancing their knowledge was very impressive. The Steering Committee noted the AHWP is now a very focused and committed regional group which is impressively lead by Dr Tan. Members also noted an additional report concerning the Kuala Lumpur event which was provided by Dr Tan and tabled during the Meeting.

4.1.5 The Chair also advised the Meeting that the AHWP is considering whether it should develop its own internet website. The Steering Committee indicated it would be supportive of the AHWP developing a website and agreed to a request from the AHWP Vice-Chair, Mr Ed Woo, that an internet hyperlink be established with the GHTF website once the AHWP site is operational.

Action:

GHTF Chair to advise the AHWP Vice-Chair that the Steering Committee is supportive of the AHWP developing a website and agreed that an internet hyperlink be established with the GHTF website once the AHWP site is operational.

ITEM 4.2: AMERICAS WORKING GROUP

4.2.1 The Steering Committee noted the report provided by the Regional Advisor of the Pan American Health Organisation (PAHO), outlining an overview of the Americas Working Group's recent activities (which have occurred since the second Meeting). The Meeting was advised the next International Workshop is scheduled to be held in Chile sometime during late 2001.

ITEM 4.3: REPORT FROM THE SINO-US WORKSHOP ON QUALITY SYSTEM REGULATION AND ISO REQUIREMENTS FOR MEDICAL DEVICES, KUNMING, CHINA: 11-13 SEPTEMBER 2001

4.3.1 The Chair advised the Meeting of a recent Sino-US Workshop on Quality System Regulation and ISO Requirements for Medical Devices which was held in Kunming, China on 11-13 September 2001.

4.3.2 The Workshop was principally arranged by the US Department of Commerce (DoC) and conducted as an activity of the Medical and Pharmaceutical Industries Subgroup of the US-China Joint Committee on Commerce and Trade. Substantively, the Workshop program focused on the international adoption of Quality Systems-based regulatory approaches. The program was endorsed as an outreach activity of the GHTF and was designed to draw upon and emphasise regulatory concepts developed by the GHTF and its Study Groups.

4.3.3 The Chair advised she had to decline an invitation to personally deliver the introductory remarks to the Workshop due to Parliamentary commitments in Australia at the time. However, the Chair extended her thanks and appreciation to Mr Michael Gropp who read a prepared speech on her behalf. Mr Gropp was one of several GHTF Members who attended the Workshop as presenters.

4.3.4 Members noted there were approximately 150-160 delegates at the Workshop which was a successful event from the viewpoint of opening dialogue, creating engagement and raising awareness of regulatory practices in other countries.

4.3.5 The Chair advised she has received a draft report on the Workshop from the US DoC. The DoC has indicated the final version may be distributed to Members once it has been cleared by the US Embassy in Beijing.

Action:

GHTF Secretary to distribute the Kunming Workshop report to Members once the US Department of Commerce provides the final, approved version.

ITEM 5: GHTF STUDY GROUP MATTERS

ITEM 5.1: STUDY GROUP 1

ITEM 5.1.1: UPDATE - STUDY GROUP 1 WORK PLAN

5.1.1.1 At the second Meeting, the Steering Committee endorsed the SG1 Work Plan and priorities presented, but requested further information regarding SG1's estimated delivery times for work items, the number documents to be progressed and the resources required to achieve this. An updated SG1 Work Plan was included among the agenda papers.

5.1.1.2 With regard to SG1's on-going work concerning in-vitro diagnostic products, a Member noted that a reference standard relating to traceability requirements has, or was about to be adopted in Europe, but there was nothing comparable in force in the USA. As its work program progresses, SG1 was requested to monitor implementation of the European IVD Directive to ensure the regulation of these products remains as harmonised as possible.

5.1.1.3 In concluding, the Committee endorsed the revised SG1 Work Plan. A Member complimented the SG1 Chair on the format of the revised Plan and the Committee agreed with the suggestion that this format be adopted when the four Study Group Work Plans are presented in a standard format for posting on the GHTF website.

5.1.1.4 A Member noted this was an action item from the second Meeting and requested a progress report. The Chair advised the action item will be finalised after the Committee gives its final endorsement to all four Study Group Work Plans.

Action:

Further to the second Meeting, GHTF Secretary to present the Study Group Work Plans in the standard format agreed upon and post them on the GHTF website once the four Plans are endorsed by the Steering Committee.

ITEM 5.1.2: REVIEW AND APPROVAL OF THE SG 1 DOCUMENT, *"MEDICAL DEVICES CLASSIFICATION"* AS A "FINAL DOCUMENT"

5.1.2.1 At the second Meeting, the Committee was advised that SG1 would further review the Working Draft document, *"Medical Devices Classification"* and aim to have it ready for consideration as a "final document" by the Steering Committee at the 3rd Meeting.

5.1.2.2 The Meeting noted that following the postponement of the Study Group meetings scheduled for mid-October 2001 in Barcelona, the document will now receive further consideration when the postponed SG1 Meeting can be re-scheduled.

Action:

When completed, the SG1 Chair to forward the document, *"Medical Devices Classification"* to the GHTF Secretary for inclusion in the agenda of the 4th Steering Committee meeting.

5.1.2.3 The SG1 Chair also advised a similar delay has occurred with the incorporation of requirements for IVD's into the document, *"Labelling for Medical Devices"*. The Meeting noted this item will also be progressed at the next SG1 Meeting, the aim being to have a "Working Draft" ready for posting on the GHTF website.

ITEM 5.1.3: STUDY GROUP 1 MEMBERSHIP

5.1.3.1 At the second Meeting, the Committee agreed that the Study Group Chairs be asked to review and amend their current memberships in terms of the new procedural documents and provide a list to the Chair, indicating which jurisdictions, organisations, etc each of their Members represent.

5.1.3.2 The SG1 Chair advised that participation in SG1 Meetings has significantly increased in recent times due to attendance by observers whose expertise is required for the consideration of issues relating to in-vitro diagnostic products. Members advised they were seeking the above information primarily in relation to the regular SG1 membership list.

Action:

The Study Group 1 Chair to review and amend the current SG1 membership list in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of the Group's Members represent).

ITEM 5.2: STUDY GROUP 2

ITEM 5.2.1: UPDATE - STUDY GROUP 2 WORK PLAN

5.2.1.1 At the second Meeting, the Steering Committee endorsed the SG2 Work Plan and priorities presented, but requested further information regarding SG2's estimated delivery times for the current and proposed work items, the resources required and further rationale/a feasibility assessment for the Postmarket Surveillance project. An updated SG2 Work Plan was included among the agenda papers.

5.2.1.2 The Committee noted the current and completed work items, but raised further queries in relation to the proposed Postmarket Surveillance project. Members' comments included -

- Whether SG2 was the most appropriate Group to carry this project forward, since some of its scope would overlap with SG1;

- Postmarket Surveillance studies are relatively new to the medical devices sector, but there exists many years of experience within the medicines industry, expertise in academia, scientific journals, etc. It was suggested that some of the established approaches be examined as a 'lead-in' to the project;
- The EU Medical Device Directives include requirements for postmarket surveillance studies and some of the more innovative manufacturers have already been producing some high quality work (after considering the approaches which have been adopted by the medicines industry); and
- There should be an examination of the differences in the various regulatory requirements at the outset of the project.

5.2.1.3 The Steering Committee agreed there is value in the proposed Postmarket Surveillance project, but prior to giving its endorsement to proceed, requested the SG2 Chair to more clearly define the work item eg. specify the timeframe and resources required, undertake a feasibility assessment and give consideration to the various issues raised, including regulatory factors, requirements for manufacturers, content of the project, etc.

Action:

1. The SG2 Chair to forward a revised Work Plan to the GHTF Secretary in the format presented for Study Group 1, for inclusion in the agenda of the next Steering Committee Meeting.
2. The SG2 Chair to more clearly define the proposed Postmarket Surveillance project in line with Members comments and forward an updated proposal to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

ITEM 5.2.2: STUDY GROUP 2 MEMBERSHIP

5.2.2.1 At the second Meeting, the Committee agreed that the Study Group Chairs be asked to review and amend their current memberships in terms of the new procedural documents and provide a list to the Chair, indicating which jurisdictions, organisations, etc each of their Members represent.

5.2.2.2 The Committee noted the updated SG2 Membership list which was included among the agenda papers. Some Industry Members commented they were pleased with the balance between government and industry Members on this Study Group.

ITEM 5.2.3: CONSIDERATION OF STUDY GROUP 2 DOCUMENTS

5.2.3.1 The Steering Committee gave consideration to the status (as either "Proposed" or "Final" Documents) of the following Study Group 2 Documents which were included among the agenda papers -

i) Global Medical Devices Competent Authority Report (N9R10);
ii) Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3);
iii) Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices (N31R6);
iv) Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (N33R9); and
v) Application Requirements for Participation in National Competent Authority Report Exchange (N38R6).

5.2.3.2 The Meeting was advised that the document, *"Global Medical Devices Competent Authority Report **(N9R10)**"* is an update of an earlier version (Revision 5) which was endorsed as a "Final Document" during the 7th GHTF Conference. R5 is the current version posted on the GHTF website and the Meeting noted R10 is an update which only contains minor differences to the earlier version.

5.2.3.3 The Steering Committee endorsed the addition of the SG2 document, *"Global Medical Devices Competent Authority Report (N9R10)"* to the GHTF website as a "Final Document" in place of the existing version (R5).

Action:

GHTF Secretary to post the SG2 document, *"Global Medical Devices Competent Authority Report (N9R10)"* to the GHTF website as a "Final Document" in place of the existing version (R5).

5.2.3.4 The Meeting was advised that SG2 has reached consensus on the document *"Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format **(N32R3)**"* and was now seeking the Steering Committee's approval to post this version on the GHTF website as a "Proposed Document", for public comment.

5.2.3.5 The Steering Committee endorsed the addition of the SG2 document, *"Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3)"* to the GHTF website as a "Proposed Document".

5.2.3.6 Some Members noted the document included among the agenda papers included the header, "N32R2". The Meeting was advised of an error in the header and that the document included among the agenda papers (dated 22 February 2001) was "N32R3".

Action:

1. GHTF Secretary to post the SG2 document, *"Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format (N32R3)"* to the GHTF website as a "Proposed Document".
2. GHTF Secretary to amend the document header to indicate the correct revision number, "R3".

5.2.3.7 The Meeting was advised that SG2 has not reached consensus on the document, *"Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices **(N31R6)**"*, but was now seeking the Steering Committee's approval to post this version on the GHTF website as a "Proposed Document", in order to obtain additional external/public comment.

5.2.3.8 While acknowledging that a significant effort had already been invested in the document, Members expressed strong reservations at the suggestion of advancing a draft guidance document to "Proposed Document" status in the absence of a consensus position from the authoring Study Group.

5.2.3.9 Members also expressed concerns in relation to how a "Proposed Document" with this degree of uncertainty may be received by stakeholders, given the current focus upon quality and safety issues in the world's health care systems. Specifically, Members were concerned that its scope does not adequately address situations revolving around the misuse or abuse of a medical device.

5.2.3.10 Further, the Meeting noted that recent studies (in countries including the United Kingdom, Australia and Canada) are indicating that costs within health care systems are increasing due to the failure, misuse, etc of medical devices. Members believe the document needs to also address the broader issue of identifying the 'root cause' of problems and further investigate how errors throughout the whole health care system may be prevented (where relevant to the use of medical devices).

5.2.3.11 In addressing these broader questions, the Committee agreed it was important to also recognise that problems are not necessarily due to a problem with a device, although manufacturers can invariably become involved since patients who have suffered harm, often lay blame with a product (whether rightly or wrongly).

5.2.3.12 The Committee indicated it was not seeking to prevent further progress with this document, but agreed that its scope, purpose, background and intended use need to be amended to incorporate the latest public health information on the topic. Members also agreed to provide further comments on the document directly to the SG2 Chair (and copied to all other Members for information), by 31 December 2001, to enable SG2's further consideration prior to the next Steering Committee Meeting.

Action:

1. Members to provide further comments on the SG2 document, *"Medical Devices: Post Market Surveillance: Proposal for Reporting of Use Errors with Medical Devices (N31R6)"*, to the SG2 Chair by 31 December 2001 (copying their comments to all other Members for information); and
2. SG2 to review the document in line with the Committee's consideration and additional comments received; and forward a revised version to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

5.2.3.13 The Meeting was advised that SG2 has not reached consensus on the document, *"Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports **(N33R9)**"*, but the Group considered that moving it to "Proposed Document" status to receive additional external/public comment would clarify how to proceed.

5.2.3.14 The Meeting noted that although no consensus has been reached, SG2 considers some guidance is needed for countries developing reporting regulations, but also expressed some concern that it would be undesirable if countries with already established programs were expected to harmonise to this guidance, as currently presented.

5.2.3.15 Members agreed further work on this document was required prior to posting on the GHTF website as a "Proposed Document". Members' comments included -

- an amendment to the Introduction will eventually be required (to specify a range from **2 days** to 30 days) once Australia's new medical devices legislation is passed by its Parliament;
- a recognition that it is unlikely there will ever be agreement between the Founding Members to one, single adverse event reporting timeframe;
- whether there is a problem with the document ultimately reflecting the different reporting timeframes of each GHTF Founding Member. It was suggested this may assist countries with adverse event reporting systems currently under development to choose a timeframe most suited to their own needs;
- there is a need to ensure 'best practice' worldwide, so that, if there are a number of options available, then a manufacturer knows which timeframe to select to ensure they are acting in the best public health interests;
- manufacturers currently have statutory obligations to adhere to, but these may differ to what is considered 'best practice' between different jurisdictions;
- irrespective of differing reporting times, there is a regulatory expectation that any serious public health threat is reported to the appropriate authority immediately. Sound administrative processes can be set in place to determine how and when additional information should be subsequently provided.

5.2.3.16 In concluding, the Committee agreed the scope, purpose, background and intended use needs to be amended in line with Members' comments on the document. Members also agreed to provide further comments on the document directly to the SG2 Chair (and copied to all other Members for information), by 31 December 2001, to enable SG2's further consideration prior to the next Steering Committee Meeting.

Action:

1. Members to provide further comments on the SG2 document, *"Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (N33R9)"*, to the SG2 Chair by 31 December 2001 (copying their comments to all other Members for information); and
2. SG2 to review the document in line with the Committee's consideration and additional comments received; and forward a revised version to the GHTF Secretary for inclusion in the agenda of the next Steering Committee Meeting.

5.2.3.17 The Steering Committee agreed the SG2 document, *"Application Requirements for Participation in National Competent Authority Report (NCAR) Exchange **(N38R6)**"*, represents a 'blueprint' for a NCAR Exchange Program, but requires further review by SG2 (in terms of the issues raised under Item 2.3).

ITEM 5.3: STUDY GROUP 3

ITEM 5.3.1: PROPOSED MERGER OF SG3 AND SG4

5.3.1.1 During the second Meeting, the Committee noted the manner in which the activities and work programs of the two Study Groups complement each other and agreed that the SG3 Chair and Interim SG4 Chair develop a proposal to establish a merger between the two, for consideration during the third meeting. The proposal outlined two alternate options and was included among the agenda papers.

5.3.1.2 Members noted option 1 proposed to maintain Study Group 4 (SG4) which was considered to convey the following advantages -

- Study Group 3 (SG3) and SG4 can work in parallel and accomplish more by having separate but coordinated focuses;
- More appropriately assign individuals from both regulators and industry since both scope areas are large and require distinctly different expertise and background experience;
- Better alignment and participation with relevant standards being developed with ISO; and
- More specific focus for SG4 with clear direction and priorities established by the Steering Committee.

5.3.1.3 Members noted option 2 proposed to discontinue SG4 and merge part of its membership with SG3 and this was considered to convey the following advantages -

- Founding members would require fewer people to participate in GHTF Study Group activities; and
- Eliminates any duplicity of work by merging all quality system aspects under one study group. There would be no need to coordinate with a separate Study Group.

5.3.1.4 Following discussion of the options, the Committee agreed that SG4 should complete its current work program (as endorsed at the second Meeting), but acknowledged there is a 'sunset' provision for this study group.

5.3.1.5 Once the current work program is completed, the Committee also agreed that SG4 be merged with SG3 and from the new, combined Study Group, an ad hoc subset of Members would be established to undertake a 'maintenance function' relating to the on-going management and updating of SG4's "Final Documents".

5.3.1.6 Members then sought specific advice on SG4's outstanding work items and the number of meetings (and timeframe) required to complete these items. The Interim SG4 Chair advised of the following, outstanding work items -

- Supplement No.5: Audit Reports (relating to confidence building programs) which is approximately 95% complete;
- SG4, N32: Guidance on the Development of Audit Strategies; and
- Supplement No.xx: Development of the Common Audit Report Format.

5.3.1.7 The Meeting was advised that after taking into account the periods required for public consultation and Steering Committee consideration/approval of guidance documents, it should be possible to complete these work items during two SG4 Meetings to be held by May 2003.

5.3.1.8 The Committee therefore reaffirmed Dr Horst Frankenberger as the Interim SG4 Chair and agreed that SG4 convenes two further meetings before May 2003 to complete the outstanding work items listed above. The Committee also agreed that after May 2003, the aforementioned merger with SG3 and 'maintenance function' for SG4 documents will take effect.

Action:

GHTF Chair to write to all SG3 and SG4 Members advising of the Committee's decisions with regard to the future direction and structure of the two Study Groups.

ITEM 5.3.2: STUDY GROUP 3 MEMBERSHIP

5.3.2.1 At the second Meeting, the Committee agreed that the Study Group Chairs be asked to review and amend their current memberships in terms of the new procedural documents and provide a list to the Chair, indicating which jurisdictions, organisations, etc each of their Members represent.

5.3.2.2 The Committee noted the updated SG3 Membership list which was tabled during the Meeting. The background to this issue was the discussion at the second Meeting concerning the participation in Study Group meetings by representatives of conformity assessment bodies.

5.3.2.3 In view of this previous discussion, the SG3 Chair advised the meeting of her wish to retain one member who previously worked for Japanese industry, but is now employed by a Japanese conformity assessment body (CAB). The person is an important member of the Study Group due to his risk management expertise. The Committee was advised that although the person is now employed by a CAB, his attendance at SG3 Meetings has been agreed to by the SG3 Chair and is sponsored by the JFMDA.

5.3.2.4 A Member advised of a provision in the "*GHTF Roles and Responsibilities"* procedural document (Paragraph 10.2 - Study Group Membership) which states, in part -

"It is also recommended that representatives from conformity assessment bodies only be invited to participate in Study Group activities if they are appointed on behalf of a particular regulatory authority".

5.3.2.5 Based on this provision, the Committee therefore questioned the validity of the aforementioned CAB representative on SG3 being sponsored by the JFMDA. Other Members advised that CAB representatives are appointed for their specific expertise, but are not appointed as, and do not represent the interests of regulatory agencies.

5.3.2.6 The Meeting was advised the background to this procedural rule was an earlier agreement that Study Group Members would represent either a regulatory agency or an industry association and that CAB representatives would be categorised as 'regulators' (albeit, very loosely). Another Member advised that the alignment of CAB representatives with industry associations may cause concern for CABs who primarily undertake public administration functions.

5.3.2.7 In summarising, the Chair advised that an amendment to the "*GHTF Roles and Responsibilities"* procedural document will be required if the aforementioned CAB representative is to retain his position on SG3. In noting the SG3 Chair's request for this to occur, the Committee agreed to amend paragraph 10.2 of the procedural document to clarify that CAB representatives may be appointed to Study Groups by either regulatory agencies or industry associations for their specific expertise (but not as a representative of the nominating organisation).

Action:

1. GHTF Secretary to prepare a draft amendment to Paragraph 10.2 of the "*GHTF Roles and Responsibilities"* procedural document, to clarify that CAB representatives may be appointed to Study Groups by either regulatory agencies or industry associations for their specific expertise (but not as a representative of the nominating organisation).

2. GHTF Secretary to circulate the draft amendment to Members for comment and once endorsed by the Steering Committee, incorporate the amendment into the final procedural document currently posted on the GHTF website.

ITEM 5.3.3: POSSIBLE REMOVAL OF ISO 13488 FROM THE LIST OF TC 210 QUALITY MANAGEMENT SYSTEM STANDARDS

5.3.3.1 The Meeting was advised of an ISO proposal concerning the possible removal of ISO 13488 from the list of TC 210 Quality Management System Standards. A Briefing Paper prepared by the ISO TC210 secretariat was included among the agenda papers.

5.3.3.2 The SG3 Chair referred the Briefing Paper to the Steering Committee, seeking consideration of the proposal and the establishment of a GHTF position on this matter.

5.3.3.3 During discussion, there were numerous differing views and the Steering Committee was unable to reach a consensus position on the proposal. The SG3 Chair advised the issue would be further discussed during the SG3/TC210 Meeting being held in Barcelona from 13 October 2001. To assist with further consideration of the proposal, the SG3 Chair advised she would obtain a summary from this meeting for distribution to Members.

Action:

1. The SG3 Chair to forward a summary from the SG3/TC210 Meeting held in Barcelona from 13 October 2001 to the GHTF Secretary for circulation to Members.
2. Steering Committee Members to provide written comments to the GHTF Chair on the ISO proposal concerning the possible removal of ISO 13488 from the list of TC 210 Quality Management System Standards.

ITEM 5.4: STUDY GROUP 4

ITEM 5.4.1: STUDY GROUP 4 MEMBERSHIP

5.4.1.1 At the second Meeting, the Committee agreed that the Study Group Chairs be asked to review and amend their current memberships in terms of the new procedural documents and provide a list to the Chair, indicating which jurisdictions, organisations, etc each of their Members represent.

5.4.1.2 The background to this issue was the discussion at the second Meeting where some industry Members expressed concern at the lack of balance in the SG4 Membership (with respect to the government-industry ratio).

5.4.1.3 In view of this previous discussion, the Interim SG4 Chair advised that SG4 currently comprises 13 Members - 10 regulators and 3 industry. There are no industry Members from Japan, Canada or Australia and the Interim SG4 Chair sought Members' advice on representation from these countries. The Meeting noted the advice from the JFMDA and MEDEC Members that these associations may be able to nominate three new Members to SG4 (two and one respectively) to assist with addressing the current imbalance.

Action:

1. JFMDA and MEDEC to advise the Interim SG4 Chair and GHTF Chair/Secretary when their new nominations to the SG4 Membership have been finalised.

2. The Interim SG4 Chair to review and amend the SG4 membership list in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of the Group's Members represent).

ITEM 6: GHTF STRATEGIC REVIEW - STEERING COMMITTEE WORKING GROUP OUTCOMES

ITEM 6.1: DRAFT GHTF STRATEGIC PLAN: 2002-2006

6.1.1 At the second Meeting, the Steering Committee considered the six Strategic Theme reports prepared by the Working Groups established after the first Meeting. The aim of the discussion was to summarise the six reports to allow for the subsequent development of a Draft Strategic Plan which identifies a number of key outcomes/ deliverables; and how these may be achieved.

6.1.2 Members agreed that the suggested approaches outlined in the Strategic Theme reports be included in a draft Strategic Plan for consideration at the third Meeting. A copy of the first draft (Revision 1) of the GHTF Strategic Plan: 2002 - 2006 was included among the agenda papers.

6.1.3 The Vice-Chair re-introduced the subject and facilitated the following discussion and outcomes. At the outset, Members reiterated that the Strategic Plan should attempt to 'map the course' by which the Steering Committee will be measured over the next five years, that the Plan would be characterised by goals (to be derived from the six strategic themes) and these goals would subsequently define a number of key deliverables to be achieved within specified timeframes.

6.1.4 In discussing the draft Plan, Members considered that further clarification is required to address - "who the plan is for", the final form in which the Plan would be presented and the relationship between the Plan and the GHTF Guiding Principles (without necessarily restricting the Plan to the contents of the latter).

6.1.5 During the discussion, Members raised the following points which need to be further addressed or taken into account when the Plan is being re-drafted -

- Does the GHTF wish to be a 'reactive' or 'pro-active' organisation. (To date, the former has generally prevailed although 'pro-active' measures have become more prevalent in recent times);
- The ability to achieve any goals specified by the Plan will largely be governed (and ultimately constrained) by resource availability;
- It will be important to reflect upon what the GHTF has already achieved since 1992, noting the considerable global changes which have occurred since then;
- Longer term goals should not be linked to highly specific timeframes; and
- A successful Strategic Plan does not stagnate on a bookshelf and Members would know a good Plan has been developed when it actually assists with resolving a problem which may arise in the future.

6.1.6 In considering possible goals, one Member suggested the Founding Members concentrate upon adoption of the Final Guidance Documents (noting that considerable resources had already been invested in the development of these documents). It was considered that once a high degree of harmonisation had been achieved among the Founding Members, a further 'flow-on' effect may then be seen in countries with regulatory systems currently under development.

6.1.7 In considering possible goals related to training, Members agreed the GHTF is not primarily a 'training organisation' and does not possess the expertise to address specific issues for individual countries eg. how a specific guidance could or should be adopted by a country for their own unique situation. Unique circumstances relate to a country's own sovereignty and accordingly, must be addressed by that country. However, the GHTF's expertise can be utilised in training programs, primarily by selected experts presenting Final Guidance Documents and advising how these represent a framework for the regulation of medical devices.

6.1.8 It was suggested the Plan clearly specifies two main focal points for the GHTF -

i) that the goals for the Plan are primarily aimed at the five Founding Members, while ensuring the GHTF remains an organisation that is viewed and utilised by other regions/countries as a 'launching platform' for developing and implementing their own requirements; and
ii) the Plan be used to measure the performance of the Steering Committee and Study Groups.

6.1.9 The Committee agreed that the Plan include the above measures of accountability as its main focal points. While acknowledging the first draft presented among the agenda papers contained a significant quantity of important information, discussion then turned to the Plan's format and presentation.

6.1.10 Members decided the draft Plan needed to be re-drafted in order to present a more 'outcome oriented' document and agreed that the re-drafting be done in the following format -

- Identify the **"Vision"** and determine how all encompassing this vision should be ie. to address the Plan only or the broader GHTF processes;
- Identify the **"Mission"** and express how the Plan will contribute to realisation of the "Vision" (eg. how many meetings has the Steering Committee convened, how many Study Group meetings have been convened, address the over-sighting and approving of Study Group work items, hosting of GHTF Conferences, etc);
- Identify the primary **"Goals"** – six main themes have already been identified, but it may be more appropriate to re-name or re-work these under the new format; and
- Identify the **"Actions"** with specified **"Timeframes"** ie. the “how to deliver” part of the document comprising short, simple, measurable descriptors with timelines that are drawn from the previous efforts of the six Working Groups.

6.1.11 With regard to the 'actions', a Member suggested there was a need to insert a rationale statement for each item. It was considered that presentation of the Plan in the above format will clearly allow the GHTF to demonstrate its progress and achievements during the forthcoming five year period.

6.1.12 In relation to participation by other countries/regions in the GHTF, Members clearly stated the Plan must not be presented in a manner which suggests the GHTF is the exclusive domain of the five Founding Members. The Plan must not exclude any participant or potential future Member, particularly those who have already demonstrated a legitimate interest in the organisation and the competence to participate in a constructive manner.

6.1.13 While acknowledging the composition of the Steering Committee could be potentially different in future years, Members agreed that it was currently important to focus upon what may be realistically achieved by the current membership during the next five years (taking into account each Member's resource constraints).

6.1.14 To ensure there is no chance of the Strategic Plan or GHTF being incorrectly perceived as a 'closed shop', the Committee agreed to use the term, "Members of the GHTF" in the Plan (as opposed to "Founding Members"), noting that the Members of the Steering Committee constitute the organisation's governing body.

6.1.15 With regard to re-drafting the Plan in the format agreed above, the Committee also agreed this be undertaken by a small drafting committee lead by Mr Vale and Ms Maclachlan; and also comprising Mr Gropp, Mr Murray and Mr Freeman.

Action:

The Vice-Chair to convene a preliminary meeting with the TGA to progress the draft Strategic Plan (in the manner agreed by the Committee); and subsequently liaise with the remaining Members of the drafting committee in order to prepare an updated draft Plan for consideration and/or endorsement at the next Meeting.

6.1.16 To further assist the re-drafting process, the Vice Chair asked Members to state the indicators they believe would provide evidence of success for the GHTF. The following indicators were listed -

- implement the outcomes of the GHTF Study Groups;
- ensure all the 'pillars' of a global model for medical device regulation are set in place;
- evaluate and implement the Global Vigilance Exchange System;
- evaluate and implement the SG1 document, *"Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)"*;
- full adoption of Final GHTF Guidance Documents;
- implementation of fundamental guidance documents which provide harmonisation for regulatory controls in both, the pre- and post-market phases;
- "single process replaces multiple processes" and "regulatory burden has been reduced" - harmonisation has been implemented to an extent that the regulatory burden has been reduced;
- a new approach to conformity assessment in Japan;
- GHTF training is being delivered;
- "signs of broader uptake of GHTF principles" - remove barriers and further encourage the rest of the world to follow GHTF principles as soon as possible;
- quantify the number of developing countries that are adopting GHTF principles;
- have the capacity to identify new and emerging technologies (and related issues) and how to appropriately handle these technologies; and
- increase the GHTF's relevance to the broad public health agenda and other relevant stakeholders.

ITEM 6.2: DRAFT GUIDELINES - REGULATORY REQUIREMENTS FOR NEW AND EMERGING TECHNOLOGIES

6.2.1 Following consideration of the Strategic Theme report prepared by Working Group 1 (WG1) during the second Meeting, the Steering Committee agreed that WG1 identify a number of 'new technologies', select two 'hot topics' for further consideration and proceed with the development of a draft guideline for the Committee's consideration at the third Meeting.

6.2.2 One of the WG1 co-convenors advised there had been very limited responses and support for progressing this issue since the second Meeting. It had been suggested that genetic testing/screening and medical devices incorporating biological tissues be considered as the two 'hot topics'.

6.2.3 In view of the lack of progress, the Meeting was asked to reconsider its level of support for this issue and confirm whether the appropriate resources would be made available to commence, and more importantly, complete the task.

6.2.4 There was general support for the two topics identified, but Members agreed the issue has become a secondary priority at this point in time. However, to progress the issue in the future, the Committee agreed with a suggestion that it be included for discussion during the Plenary Session of the 9th GHTF Conference as a "Special Topic" item.

Action:

GHTF Secretary to include the issue, *"Regulatory Requirements for New and Emerging Technologies"* in the agenda of the 9th GHTF Conference's Plenary Session as a "Special Topic" item.

ITEM 6.3: WG3 UPDATE - COMMON METHOD OF EXCHANGING REGULATORY INFORMATION AND MUTUAL ACCEPTANCE OF DATA REQUIREMENTS/NON-DUPLICATIVE

6.3.1 During the second Meeting, the Steering Committee considered the Strategic Theme reports prepared by Working Group 3 and noted they represented a 'status report' on the Group's progress to date. The Committee agreed that the Group continue its work, further refine the proposals, merge the two documents and present one, new document for consideration during the third meeting.

6.3.2 The Meeting noted this action item had largely been surpassed by the development and consideration of the draft GHTF Strategic Plan at Item 6.1 which incorporates the major issues already identified by WG3. The Committee agreed that any further input on this topic from WG3's co-convenors now be referred directly to the 'drafting committee' established under Item 6.1.

ITEM 6.4: WG4 UPDATE - EVOLVING REGULATORY SYSTEMS

6.4.1 During the second Meeting, the Steering Committee considered the Strategic Theme report prepared by Working Group 4 and noted it included recommendations relating to the participation of countries with emerging regulatory systems in the GHTF processes, training and; advocacy and outreach.

6.4.2 Members also raised a number of issues requiring further consideration and agreed that WG4 further refines its report and presents an updated version to the third Meeting. A copy of WG4's updated report was included among the agenda papers.

6.4.3 One of the WG4 co-convenors advised the majority of issues raised during the second Meeting had been addressed in the updated report, but noted this action item had largely been surpassed by the development and consideration of the draft GHTF Strategic Plan at Item 6.1, which incorporates the major issues already identified by WG4. However, the WG4 co-convenor invited further comments on the report which could be referred to the 'drafting committee' established under Item 6.1.

ITEM 7: GHTF TRAINING

7.1 During the second Meeting, the Chair advised of a funding proposal being developed by the TGA for consideration by an Australian Government aid agency. Since the second Meeting, the proposal was not progressed as the TGA became aware of a comparable funding bid developed by AdvaMed (which was at a more advanced stage). The TGA and AdvaMed agreed it would be beneficial to 'pool' resources and this bid was discussed under Item 2.4.

7.2 Members also gave further consideration at the second Meeting to a policy relating to GHTF Training, the handling of any formal requests for training and a proposal to establish a "GHTF Training Institute". With regard to the latter, Members noted a major constraint to the establishment and maintenance of an Institute is the absence of any guaranteed source of funding. While not rejecting the proposal at this stage, Members agreed the establishment of a formal "GHTF Training Institute" is unlikely in the near future.

7.3 With regard to the broader 'training' issue, Members made the following comments and suggestions -

- Each of the GHTF Study Groups could be asked to develop a Training Curriculum or Manual encompassing the expertise and focus of each Group. This could include copies of presentations recently delivered to various forums around the world;
- A "GHTF Training Institute" could possibly be linked to a Permanent Secretariat;
- Training should be a part of the regional activities undertaken by the Founding Members and should focus upon the harmonised requirements the GHTF has already agreed to;
- The need for the Committee to formally appoint endorsed 'GHTF Trainers';
- It will be important for the Committee to somehow maintain control over the content of the material being used for training purposes; and
- Consider the relationship between 'training' (as it will be addressed in the GHTF Strategic Plan) and the various GHTF Training initiatives which are developed in the future.

7.4 To address these and other related issues, the 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 next Meeting.

Action:

Mr Brekelmans and Mr Gropp to prepare a framework for a draft procedural document addressing the future conduct of GHTF Training and forward the 'framework' to the GHTF Secretary for inclusion in the next meeting agenda.

ITEM 8: ESTABLISHMENT OF A PERMANENT SECRETARIAT

8.1 During the second Meeting, Members gave further consideration to the establishment of a permanent GHTF Secretariat and noted the Strategic Theme report prepared by Working Group 6 identified a number of "pros" and "cons" relating to this matter.

8.2 Members also noted another suggestion during the second Meeting from the US FDA that it may be possible to establish a "Global Secretariat" comprising a 'core group' (which would be situated with the current Chair) and several part time staff in different regions, each with clearly defined responsibilities. Members noted this approach would create a GHTF liaison point in different parts of the world, but also recognised that the current GHTF Chair would accept most of the responsibilities.

8.3 Prior to the third Meeting, the Chair requested further details on this suggestion and an updated proposal was tabled during the Meeting. Members noted the proposal outlined three possible options for a GHTF Secretariat -

i) the current model ie. a 'nomadic' secretariat which moves with the rotating Chair;
ii) a Permanent Single Location - this option is comparable to the ICH model where the secretariat has a permanent location and is independent of any given Member; or
iii) a Permanent Distributed Location ie. a network/global model.

8.4 The Meeting was advised that Option 3 would involve each 'regulatory' Founding Member designating one staff member to become part of a global secretariat network with defined responsibilities. Members noted the network could establish or provide:

- a permanent home for the GHTF web site;
- a permanent home for paper documents and archived records (perhaps stored in quintuplicate);
- resource materials for training;
- up-to-date tracking of the implementation status of GHTF documents, on a member-by-member basis;
- continuity in logistical support for larger meetings;
- a regional resource to regulatory and industry groups; and
- a liaison for the Study Group Chairs.

8.5 Members were also advised of the additional issues concerning industry contributions to the operation of the GHTF Secretariat and whether there should also be an industry staff member serving as a liaison to industry (or whether this activity is adequately covered by the Steering Committee Members themselves).

8.6 Following discussion of the three options raised, there was general support to further investigate the feasibility of Option 3 from the government Members representing the USA, Australia, Canada and Europe; and industry Members representing the USA, Australia and Canada. The Japanese government and industry Members were supportive of Option 2 (the 'ICH Model') and European industry Members were supportive of Option 1 (the current model).

8.7 Some Members noted the 'ICH model' is unlikely to be suitable for the GHTF as the ICH secretariat has a revenue base and is largely self-funding, whereas the GHTF has no revenue base. Some Members who were generally supportive of Option 3 also 'flagged' that detailed consideration will be required to -

- ensure an excessive burden is not placed upon the Chair of the time;
- determine the day-to-day practicality of a network system;
- ascertain the on-going costs of maintaining such a system; and
- consider whether this will represent an interim solution which may ultimately demonstrate the need for a single location secretariat.

8.8 In noting the majority support for further investigation of the feasibility of Option 3, 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, further consider and refine the proposal to establish a global secretariat network and prepare a paper for further discussion at the next Meeting.

Action:

The GHTF Secretary to liaise with the two, former GHTF Secretaries from Health Canada and the US FDA, to further consider and refine the proposal to establish a global secretariat network for the GHTF; and prepare a paper for inclusion in the next Meeting agenda.

ITEM 9: INFORMATION ITEMS

ITEM 9.1: GHTF PUBLICITY

9.1 The Steering Committee **noted** a number of international and national activities or publications that the Chair/Secretary have recently been involved with (or arranged), which have further publicised the GHTF, its role, objectives and recent achievements.

ITEM 10: OTHER BUSINESS/LATE PAPERS

ITEM 10.1: PROPOSED COLLABORATION BETWEEN THE GHTF AND WORLD HEALTH ORGANISATION (WHO)

10.1.1 The Chair advised the Committee that she met with Mr Gerald Verollet of the WHO's Department of Blood Safety and Clinical Technology (BCT) in Geneva on Monday, 8 October 2001. Following this, a letter from Mr Verollet dated 10 October was tabled during the Meeting.

10.1.2 The Chair advised that the WHO has commenced a project entitled, *"Harmonisation on the Regulation of Medical Devices"*, which forms part of the BCT strategy for 2000-2003. The impetus behind the project is the recognition that developed countries are installing quality systems and quality control procedures, whilst few developing countries have functional systems which ensure the quality, safety and performance of medical devices.

10.1.3 The Committee noted some work has already commenced in this area via the document, *"Guidelines for the Development of Medical Device Regulations"* (which will be the subject of a Workshop during the re-scheduled 9th GHTF Conference).

10.1.4 To date, 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. The WHO has advised the guidelines now need to be expanded to include the Australian, Japanese and European regulatory schemes in order to make them relevant for global use.

10.1.5 To progress these issues, the Meeting was advised 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 has suggested that a Memorandum of Understanding (MoU) or other appropriate document be developed in order to formalise the collaboration.

10.1.6 The Committee expressed its support for this WHO initiative and agreed to provide the necessary information to assist the further development of the *"Guidelines for the Development of Medical Device Regulations"*. The Committee extended its 'in-principle' support to the development of an MoU between the GHTF and WHO and suggested that Dr Verollet be asked to provide a draft outline of the major elements which would comprise such an agreement. Members also agreed with the suggestion that Dr Verollet be invited to attend part of the next Steering Committee meeting to further discuss these issues (prior to presentation of the guidelines at the Workshop during the 9th Conference).

Action:

The GHTF Chair to respond to the WHO's letter dated 10 October 2001 advising of the Steering Committee's consideration of the WHO project, *"Harmonisation on the Regulation of Medical Devices"* and the suggested approach to progressing the issues and suggestions raised.

ITEM 10.2: RETIREMENT OF DR EGID HILZ

10.2.1 Dr Egid Hilz announced he will be retiring from the GHTF Steering Committee as of 31 December 2001. Dr Hilz was appointed to the Committee by COCIR, to represent European industry.

10.2.2 The Chair advised the Meeting that Dr Hilz has participated in the GHTF since 1993 via representation on three Study Groups and most recently, the Steering Committee. The Steering Committee expressed their appreciation to Dr Hilz for his significant contribution to the GHTF and international harmonisation.

Action:

European 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 31 December 2001 by Dr Egid Hilz's retirement.

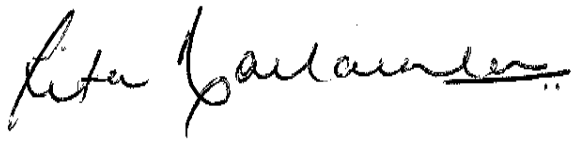
ITEM 11: NEXT MEETING

11.1 The Steering Committee agreed that its fourth meeting would be held as part of the re-scheduled 9th GHTF Conference sometime during mid-April to mid-May 2002. [*Secretary's note*: The dates and venue for the 4th Meeting will be confirmed as part of the 'action' required under Item 2.4].

11.2 The Chair closed the meeting at 3.50pm, thanked all participants for their attendance and contributions to the meeting's achievements, particularly given the challenges facing the global community at this time; and looked forward to welcoming members to the Steering Committee's fourth meeting.

11.3 The Chair especially thanked Dr Jefferys and his staff; and Mr Michael Kreutzer of the Association of British Healthcare Industries and his staff, for their assistance in London with the meeting arrangements and for hosting the Steering Committee Welcoming Reception on 11 October 2001.

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

S:\CO\TGA\TDB\GHTF\Steering Committee\3rd Meeting.october'01\minutes.doc