



**9TH CONFERENCE OF THE GLOBAL
HARMONIZATION TASK FORCE (GHTF)**

*The Global Medical Device Regulatory Model: From
Development to Implementation*

Sunday, 12 - Thursday, 16 May 2002

Singapore

Conference Report

CONTENTS

Contents	2
Introduction	3
Conference Program	3
4 th Meeting of the GHTF Steering Committee	3
Meetings of the GHTF Study Groups	5
New and Emerging Regulatory Systems	6
Asian Harmonization Working Party Information Session	6
Central / South American Information Session	7
Chinese Information Session	7
Concurrent Workshop Sessions	8
Poster Presentation Session	8
GHTF Plenary	10
Rotation of the GHTF Chair to Japan	12
Conference Social Events	12
GHTF Training: 2 nd APEC Seminar on the Harmonization of Medical Device Regulations	13
Summary	14

INTRODUCTION

The 9th Conference of the Global Harmonization Task Force (GHTF) was originally scheduled to be held immediately prior to the 9th Global Medical Devices Conference in Barcelona, Spain in October 2001. Both events were postponed due to the 11 September terrorist attacks in the USA. The GHTF Steering Committee agreed to re-schedule the 9th GHTF Conference, preferably at a location in the Asia/Pacific region.

Australia's Therapeutic Goods Administration (TGA) hosted the 9th GHTF Conference in Singapore from 12 - 16 May 2002, with the support of Singapore's Health Sciences Authority (HSA). Following the Conference, the two agencies also co-hosted a two day GHTF training event, the 2nd Asia-Pacific Economic Cooperation (APEC) Seminar on the Harmonization of Medical Device Regulations, from 17 - 18 May 2002.

The Conference was the largest GHTF gathering to date, with 220 delegates representing 29 countries. The 180 delegates who attended the APEC Seminar mainly included representatives of regulatory agencies and the medical devices industry from countries with developing regulatory systems in the Asia/Pacific, and Central and South America. The countries represented at both events are listed at Table 1.

Table 1. Countries represented at the 9th GHTF Conference and 2nd APEC Seminar

Australia Belgium Brazil Canada Chile Chinese Taipei Colombia Cuba Denmark France (*)	Germany Hong Kong Indonesia Ireland Japan Korea Malaysia Mexico Netherlands New Zealand	Panama People's Republic of China Peru Philippines Singapore Switzerland Thailand UK USA
--	--	--

(*) Not represented at APEC Seminar

CONFERENCE PROGRAM

4th Meeting of the GHTF Steering Committee

The GHTF Steering Committee is responsible for management oversight and policy setting for the GHTF. The Steering Committee was formed following the work undertaken during the US FDA's and Health Canada's Chairmanship to establish governance arrangements for the GHTF.

As GHTF Chair, Australia hosted the inaugural meeting of the Steering Committee in Sydney, Australia from 28 February - 2 March 2001. The second and third meetings have since been held in Brussels and London (during June and October 2001).

Since its inception, the Steering Committee has pursued the GHTF's international harmonization goals and embarked on a work program focused on defining the GHTF's strategic direction, the oversight and approval of the GHTF Study Group Work Plans, progressing GHTF training initiatives and maintaining a close liaison with the regional harmonization groups of Asia and Central / South America.

The major outcomes from the 4th Meeting of the GHTF Steering Committee are outlined below.

- **Further development of the GHTF Strategic Plan**

The Committee developed and agreed upon the following GHTF Vision statement -

"Enhancing the health of the public worldwide and facilitating innovation by harmonizing the global regulatory environment"; and also

progressed a Strategic Directions document to a 'near-final' draft, which was presented during the Plenary Session on 15 May 2002. This document will form the basis of the final GHTF Strategic Plan following further refinement.

- **Updates from the Global Medical Devices Nomenclature (GMDN) Maintenance Agency Policy Group**

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

The Committee also noted that some Founding Member regulatory authorities are already implementing the nomenclature and encourages other participating regulatory authorities to undertake an evaluation of the GMDN within their own jurisdictions as soon as possible.

- **Approval of two Study Group documents (one each from SG2 and SG4) as "final" GHTF Guidance Documents**

The Committee approved the following SG2 and SG4 Documents as FINAL -

- "National Competent Authority Report Exchange Criteria"; and
- "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation".

- **Progress by the Regional Harmonization Groups of Asia and Central/South America**

The Committee noted the significant progress which has been made by the regional harmonization groups from Asia and Central/South America, with the adoption of GHTF Guidance Documents.

Recent achievements include -

- the development of a regional Action Plan and translation by the Colombian Working Group of a majority of the Final GHTF Guidance Documents from English to Spanish (under the leadership of the Pan American Health Organisation);
- the establishment of an Asian Harmonization Working Party (AHWP) Technical Committee to, amongst other matters, promote and recommend the implementation of the GHTF Final Guidance Documents into the regulatory frameworks of the AHWP member economies (under the leadership of Singapore's Health Sciences Authority); and
- a survey of AHWP Members which indicated that 68% of these economies would consider the adoption and implementation of the Final GHTF Guidance Documents into their national regulatory systems.

- **Provision of GHTF training activities**

The Committee considered a draft document outlining the manner in which the GHTF will provide and facilitate training activities into the future. Following the incorporation of any final comments, the Committee agreed to adopt the document as a reference guidance and have it posted on the GHTF website.

- **Possible establishment of a permanent secretariat**

The Committee gave further consideration to five possible options for the GHTF Secretariat, including retention of the current model. The Committee agreed to establish a small Working Group to further investigate the feasibility of establishing a single permanent location for the GHTF Secretariat. The Working Group will report back to a future meeting.

Further information, including Meeting Minutes and the Membership List are available from the "Steering Committee" page of the GHTF website.

Meetings of the GHTF Study Groups

The four GHTF Study Groups have also continued to make significant progress with their substantial work programs which were developed in consultation with, and subsequently approved by the Steering Committee.

To date, the GHTF has approved 18 final Guidance Documents (including the two above) addressing the four principal pillars of medical device regulation - premarket review / regulatory requirements, device vigilance / postmarket surveillance, quality system requirements and guidance, and auditing practices. All GHTF guidance documents are available on the GHTF website

During their meetings in Singapore, the Study Groups gave further consideration to a number of key issues relating to the revision of a number of guidance documents currently under development and these are outlined in Table 2.

Table 2. Draft GHTF Guidance Documents currently under revision or development

Study Group 1

- "Medical Devices Classification"
- "Labelling for Medical Devices (including In Vitro Diagnostic Devices, IVDD's)"
- "Essential Principles for Safety and Performance of Medical Devices" to incorporate provisions for IVDDs and further revision of the guidance document
- "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance" (at the conclusion of the pilot testing currently in progress).

Study Group 2

- "Application Requirements for Participation in National Competent Authority Report Exchange"
- "Proposal for Reporting of Use Errors with Medical Devices"
- "Universal Manufacturer Report Format"
- "Timing of Adverse Event Reports"

Study Group 3

- "ISO/CD 13485 - Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes"
- "ISO/CD 13488 - Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes (Excluding Design Control Requirements)"
- "ISO 14969:200X - Quality Systems - Medical Devices - Guidance on the Application of ISO 13485 and ISO 13488"

Study Group 4

- "Supplement No.4: Compilation of Audit Documentation"
- "Supplement No.6: Observed Audits of Conformity Assessment Bodies"
- "Supplement No.x: Audit Reports"
- "SG4 Report on the Application of 'General Requirements' by Regulatory Agencies"
- "Supplement No.xx: Guidance on the Development of Audit Strategies"

New and Emerging Regulatory Systems

The Conference also featured regional information sessions on new and emerging regulatory systems in the Asian Economies, the region of the Americas and the People's Republic of China. The Sessions demonstrated a commitment and on-going progress with the adoption and implementation of GHTF guidance documents by these countries.

Asian Harmonization Working Party Information Session

Delegates attending the Asian Harmonization Working Party (AHWP) Information Session were advised of a recent survey conducted by the AHWP Technical Committee which aimed -

- to obtain input from Asian regulators on their efforts to harmonize the regulation of medical devices with the GHTF recommendations and guidances; and
- to obtain suggestions for possible regional collaboration and training.

The key results of the survey indicated that -

- 60% of the economies currently regulate medical devices;
- 20% of the economies are in the process of promulgating regulations; and
- 68% of the economies are either interested in, or considering whether to adopt and implement the GHTF guidance documents / regulatory model.

Central / South American Information Session

Delegates attending the Americas Information Session were advised that a majority of the Final GHTF Guidance Documents had been translated from English to Spanish under the leadership of the Pan American Health Organisation (PAHO) and a Colombian Working Group. Further, a regional Action Plan has been developed to -

- Organize Five Sub-Regional Workshops;
- Prepare a Country Status on Medical Devices and a Regional Profile;
- Promote Latin American and Caribbean participation in GHTF Conferences and Study Groups;
- Attend Pan American Cooperation Medical Equipment (PACME) Meetings;
- Promote the Use of MED-DEVICES List;
- Produce and Disseminate Technical Information and Publications; and
- Provide Technical Expertise to the Member Countries/Territories.

Delegates were also advised of the status of regulatory programs in the Americas Region which may be summarized as follows -

- 21 of 43 countries and territories are without legislation for medical devices;
- 7 of 22 which have legislation effectively enforce it;
- 27 without import requirements;
- 12 have attended GHTF Conferences; and
- Areas with further needs include surveillance systems, training, human resources and budgets.

Chinese Information Session

Mr Hao Heping (Director - Medical Device Department) and other officials from the State Drug Administration (SDA) of China provided a presentation of China's Medical Device Regulatory System, including an update on changes and new developments since the 8th GHTF Conference which was held during September 2000. This Session was co-moderated by Mr Jeffrey Gren from the US Department of Commerce and Mr Derek Rochford, representing EUCOMED.

The Session offered industry representatives and regulatory officials the opportunity to hear first hand about how the Chinese regulatory system is working in practice and about the SDA's plans for future regulatory developments. Specifically, delegates were provided with an update on recent changes and new developments relating to the following issues -

- Type Testing and License Renewal Requirements for Imported Medical Devices;
- Administration Rules for Clinical Trials for Medical Devices;
- Supervision & Administration Rules for Disposable Sterilized Medical Devices;
- Rules of Quality System on-site Audit for Foreign Medical Device Manufacturers;
- Classification System for Medical Devices that come in contact with blood;
- Role of the State Drug Administration of China's (SDA) Medical Device Standardization Technical Committee;

- Plans of SDA to use Auditors to verify that medical devices in China are approved and are not counterfeit; and
- Safety Testing for Medical Devices - The role of General Administration of Quality Supervision & Quarantine (AQSIQ) for electro-medical devices, the role of the Department of Labor for pressure vessels, and requirements for the new CCC Mark.

Concurrent Workshop Sessions

- **Workshop 1: The Global Medical Devices Nomenclature (GMDN)**

This Workshop was lead by Mr Maurice Freeman (Chair of GMDN Maintenance Agency Policy Group) and reinforced the message that achieving consistency in nomenclature is fundamental to the overall goal of international harmonization. Delegates were informed that the GHTF believes the GMDN will represent a major contribution to this among regulatory agencies, particularly in vigilance and the worldwide registration of products.

Mr Freeman provided an update on the GMDN and highlighted the major outcomes arising from meetings of the newly established GMDN Maintenance Agency Policy Group.

- **Workshop 2: Evaluation of Draft Guidelines for the Development of Medical Device Regulations**

This Workshop was lead by Steering Committee Member, Mr Michael Gropp (representing USA industry). The Draft Guide has been developed by the World Health Organisation (WHO) and speakers representing the WHO explained that the document provides an overview of medical device safety, its basic issues and regulatory philosophy. The Guide is primarily aimed at countries with developing regulatory systems.

Delegates were also advised the original WHO Guidelines, which primarily focused on the USA and Canadian regulatory systems, have now been expanded to include the GHTF approach. The WHO's goal is for the new guidelines to ultimately become relevant for global use by providing a general introduction to medical device regulations and an integrated reference to final GHTF Guidance Documents.

- **Workshop 3: The Regulation and Supply of Refurbished Medical Devices**

This Workshop was lead by Steering Committee Member, Mr Robert Britain (representing USA industry). There is global variation with respect to how different countries regulate refurbished medical devices imported into their economies. The Workshop elaborated on the practice of refurbishment and a number of speakers highlighted the regulatory similarities and differences between countries with both, developed and developing markets.

Delegates were also informed the supply of refurbished medical devices is becoming big business. The innovation in some equipment is rapid and the business of refurbishment is now being seriously embraced by large global manufacturers.

Poster Presentation Session

For the first time at a GHTF Conference, the program featured a Poster Presentation Session, following an invitation to delegates from the GHTF Chair to prepare posters addressing current information relevant to the international harmonisation of medical device regulatory requirements. Five posters were presented and an overview is outlined in Table 3.

Table 3. Overview of the Poster Presentation Session	
Poster 1 - Presenter: Ms Shelley Tang, Therapeutic Goods Administration, Australia	
Title The New Australian Regulatory Framework for Medical Devices	Overview This Poster presented an outline of the new Australian medical devices legislation and how it will be implemented. Delegates noted that Australia will be the first to adopt and implement the principles of the GHTF in a developed regulatory system.
Poster 2 - Presenter: Dr Jorge Garcia, Therapeutic Goods Administration, Australia	
Title TGA's Medical Device Incident Report Investigation Scheme: Regulatory Environment, Procedures, Statistics & Vigilance Exchange Activities	Overview This Poster presented an outline of Australia's Incident Report Investigation Scheme (IRIS). IRIS provides a good model for participation in vigilance activities in accordance with GHTF Study Group 2 recommendations, particularly for small nations or nations that expect to receive relatively small numbers of adverse event reports.
Poster 3 - Presenter: Mr Klauss Stinshoff, Swissmedic, the Swiss Agency for Therapeutic Products	
Title Significance of technical standards in the regulations on medical devices in the US and the EU	Overview Both, the US and the EU utilise technical standards in their regulations on medical devices and this poster investigated the legal basis for the use of standards in the two regulatory systems and outlined their differences. The consequences of these differences for the development of standards by bodies like ANSI, CEN/CENELEC and ISO/IEC; for the application of standards by manufacturers of medical devices; and for their use by regulatory authorities during market surveillance activities was discussed.
Poster 4 - Presenter: Mr Soichiro Isobe, Ministry for Health, Labor and Welfare, Japan	
Title Reform of Medical Devices Regulation in Japan	Overview Delegates noted that amendments to the Japanese Pharmaceutical Affairs Law are being made in order to bring Japan's medical devices legislation into greater alignment with the principles of the Global Harmonization Task Force (GHTF). The new system will shift the current Japanese device regulatory system away from the current manufacturing licence/approval-based system, to one based on marketing approval. The poster outlined an overview of the recent reforms to the regulation of medical devices in Japan.
Poster 5 - Presenter: Mr Rainer Voelksen, Swissmedic, the Swiss Agency for Therapeutic Products	
Title Medical Devices in Switzerland: Regulation and enforcement of Regulatory requirements by the new Swiss Agency for Therapeutic Products	Overview The poster detailed the role and organisation of Swissmedic, and basics about the Swiss regulatory framework for medical devices. Delegates were advised that Swissmedic is a public institution of the Swiss government. It's core legal basis is the Swiss Federal Law on Medicinal Products and Medical Devices. Swissmedic first commenced operation when this new Law came into force on 1 January 2002. The goal of the legislation and of Swissmedic is to guarantee that only high-quality, safe, and effective therapeutic products are placed on the market in Switzerland

GHTF Plenary

The one and a half day GHTF Plenary commenced with the official Welcoming Address by Dr Balaji Sadasivan, Singapore's Minister of State (Health and Environment). The Plenary comprised four Sessions covering GHTF Business, New and Emerging Technologies, the Global Regulatory Model and The Total Product Life Cycle: A Focus on Postmarket Surveillance and Vigilance.

• Plenary Session 1: GHTF Business

The GHTF Chair, Ms Rita Maclachlan presented the "GHTF Annual Report: 2001 - 2002" and made specific reference to the following initiatives -

- Establishment of the GHTF Steering Committee;
- the GHTF Strategic Review;
- the Global Medical Devices Nomenclature (GMDN) and the GMDN Maintenance Agency Policy Group;
- Implementation of the National Competent Authority Report (NCAR) Exchange Program; and
- Consideration given to the establishment of a permanent secretariat for the GHTF.

The full Report is available on the "Conferences" page of the GHTF website and provides an overview of these major business activities and other achievements which have occurred under Australia's Chairmanship of the GHTF.

Ms Maclachlan paid tribute to the late, Mr Gordon Higson. Delegates were advised of the significant pioneering efforts made by Mr Higson towards the international approach to harmonizing medical device regulatory requirements.

Ms Maclachlan also placed on the public record the GHTF's appreciation to a number of key, long standing GHTF Members who have recently retired or changed career paths. The significant contributions they have made to the GHTF and international harmonisation were formally acknowledged.

As consistently reported over the past 18 months, one of the Steering Committee's main tasks has been to undertake a thorough and comprehensive Strategic Review of the GHTF. Six key themes were identified and further refined, and a number of goals and actions have now been formulated as the core of the Plan. The Committee has now progressed a Strategic Directions document to a 'near-final' draft and the "GHTF Strategic Directions: 2002 - 2007" document was presented to the Conference by the GHTF Vice-Chair, Mr Brian Vale (representing Australian industry).

The presentation highlighted the new GHTF Vision Statement, "enhancing the health of the public worldwide and facilitating innovation by harmonising the global regulatory environment". The document will form the basis of the final GHTF Strategic Plan following further refinement.

The Conference was also presented with reports from the four GHTF Study Group Chairs (or Acting Chairs). Mr Maurice Freeman (SG1), Mr Kim Dix (SG2), Dr Victor Dorman-Smith (SG3) and Dr Markus Zobrist (SG4) outlined the status of each Group's work program, their current standing and future directions.

The Session concluded with presentations addressing the Regional Group updates from Asia and Central / South America. These reports were presented by Dr Clarence Tan, Chairman of the Asian Harmonization Working Party and CEO of Singapore's Health Sciences Authority, and Mr Antonio Hernandez, Regional Adviser to the Pan American Health Organisation (PAHO).

- **Plenary Session 2: New and Emerging Technologies**

Session 2 was moderated by Dr David Jefferys, Chief Executive of the UK Medical Devices Agency, and commenced with the Keynote Address, "*From Harmonization to Collaboration*" which was delivered by Ms Catherine Livingstone, Chairman of the Board of Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Ms Livingstone highlighted the impact that new and emerging technologies such as the genomic revolution, nanotechnology, miniaturisation and computing advances will have on the sector.

While applauding the move towards harmonization of the existing regulatory framework, the key question posed by Ms Livingstone was "whether we are ready to take on the challenge of migrating to a new regulatory framework: one which can deal with the timeframes and inherent complexity, yet uncertainty, of emerging technologies; which can provide a bridge between the science / industry coalition and the medical consumer; which can provide a forum for identifying the technical and social risks of a particular technology, and then provide leadership in managing the risk assessment profile of medical device products approved for market release.....and all of this is predicated on achieving mutual trust and cooperation on a scale beyond any envisaged to date".

This theme was progressed as a number of government and industry speakers then shared their views on the range of technologies they believe may emerge over the next five years. Delegates noted with significant interest, the high degree of commonality between the views.

In the subsequent panel discussion, the general conclusion emerged that it would be valuable for the GHTF to take this issue forward. The suggestion was that a timely guidance document be produced by the GHTF rather than requirements being generated independently by national authorities which would then have to be harmonized by the GHTF.

- **Plenary Session 3: The Global Regulatory Model**

Session 3 was moderated by Dr Clarence Tan and commenced with an overview of the global medical device regulatory model. This was followed by "The Scorecard", where Steering Committee Members, representing regulatory authorities from the five GHTF Founding Members, reported on progress with the implementation of harmonized GHTF Guidance Documents into their national regulatory systems.

The GHTF has had considerable success over the last decade and this was highlighted by "The Scorecard". Of course, some countries/regions have been able to move more rapidly than others since they have currently been implementing new legislation. Australia's TGA was commended for leading the world in adopting the GHTF regulatory model, with passage of the new medical devices legislation in March 2002. Nonetheless, the USA, Canada, Japan and the European Union Member States have also made significant progress with the adoption and implementation of the GHTF principles and guidance documents.

- **Plenary Session 4: The Total Product Life Cycle -A Focus on Postmarket Surveillance and Vigilance**

Session 4 was moderated by Mr Terry Slater, National Manager of the TGA, and highlighted that post marketing surveillance covers a broad range of techniques. These range from the simple recording of customer complaints through to the use of national registries, sophisticated longitudinal databases, the use of case control studies and on occasions using “a nested study” within a larger case control study.

The discussion period noted that post marketing surveillance is not just about new or high risk products. The devices sector also has to be geared for addressing long term safety issues or problems which may emerge from relatively minor changes in manufacturing. Equally, it was also recognised that low risk devices are not without hazards.

- **Rotation of the GHTF Chair to Japan**

The GHTF Chair and Secretariat officially rotates to the Ministry for Health, Labor and Welfare (MHLW), Japan on 1 July 2002 for the second half of the current three year, Asia-Pacific rotation.

The new GHTF Chair is Mr Souichi Ikegaya^(*), Director - Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau and the new Vice-Chair is Mr Kenichi Matsumoto, representing the Japan Federation of Medical Device Manufacturers (JFMDA). Mr Ikegaya and Mr Matsumoto were welcomed during the Plenary Session and made their introductory presentations at this time.

The hand-over of the GHTF Chair and Secretariat commenced in July 2002 and transition meetings involving the TGA, MHLW and JFMDA will be held in Tokyo during the first week of August. It is anticipated the rotation will be complete by the time of the fifth Steering Committee Meeting, which will be convened in Tokyo under Japan's Chairmanship from Monday, 28 - Wednesday, 30 October 2002.

The 9th GHTF Conference demonstrated the success recently achieved by the GHTF and delegates to the Conference benefited from the topical program. Importantly, this Conference also demonstrated there is a strong and clear strategic direction for the future.

^(*) On 30 September 2002, Mr Ikegaya announced that he had retired from the MHLW and that Dr Taisuke Hojo, Director - Office of Medical Device Evaluation, Pharmaceutical and Medical Safety Bureau had been appointed as the new GHTF Chair.

Conference Social Events

- **GHTF Conference Welcoming Reception**

The Welcoming Reception was held on Monday evening, 13 May at the historic CHIJMES Chapel. Delegates were welcomed to the Reception by Mr Terry Slater and enjoyed a pleasant evening away from the Conference formalities.

Formerly a convent and the seat of education for generations of Singaporean girls, CHIJMES is a unique blend of historical architecture and modern restoration. The Gothic Chapel, erected in 1890, is a showcase of plasterwork, delicate wall frescoes and stained glass. Aside from the chapel, CHIJMES also boasts Caldwell House (the oldest free-standing house in Singapore) with a sunken forecourt, waterfalls and fountains.

- **GHTF Conference Dinner**

The Conference Dinner was held on Wednesday evening, 15 May at the Jurong Birdpark, one of Singapore's major tourist attractions. The Birdpark is a tropical haven with large, open exhibits simulating natural habitats and featuring masses of birds.

The Guest Speaker for the evening was Professor Tan Ser Kiat, Group Chief Executive Officer of SingHealth (the Singapore Health Services Pte Ltd). Professor Tan is also a senior and well respected orthopaedic surgeon and he gave a broad ranging review of the impact of new medical device technologies from both, his own discipline of orthopaedics and his broader role as the SingHealth Chief Executive.

GHTF TRAINING: 2ND APEC SEMINAR ON THE HARMONIZATION OF MEDICAL DEVICE REGULATIONS

With funding provided by the Asia-Pacific Economic Cooperation (APEC), the TGA and HSA co-hosted this GHTF training seminar which immediately followed the 9th GHTF Conference on 17 - 18 May 2002.

The program featured approximately 20 expert trainers from the GHTF Study Groups, covering the regulatory agencies of Australia, the European Union, USA, Canada and Japan, and industry experts from these countries.

Dr Clarence Tan welcomed all Delegates to the Seminar and the GHTF Chair, Rita Maclachlan delivered the Opening Address. Mr Michael Gropp (a USA industry member of the GHTF Steering Committee) delivered the Keynote Address, "*The Global Medical Device Market and Regulatory Harmonization*", and this was followed by two days of training in the GHTF guidance documents, addressing the principles and technical requirements of world's best practice in medical device regulation.

The key areas covered were premarket requirements for quality, safety and performance of medical devices, postmarket monitoring and manufacturer quality assurance systems auditing and design control requirements.

The Seminar contributed towards the GHTF goal of providing educational opportunities to countries with developing regulatory systems, as well as encouraging the adoption and implementation of the GHTF principles and guidance documents into national regulatory systems.

SUMMARY

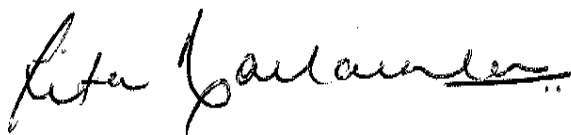
The TGA has been pleased to co-host the 9th GHTF Conference and 2nd APEC Seminar in Singapore with the Health Sciences Authority, and to also Chair the GHTF on Australia's and the Asia/Pacific region's behalf. The 9th Conference has highlighted that the GHTF continues to make significant progress with harmonizing the international regulatory requirements for medical devices.

The TGA extends its sincere thanks to all Members of the GHTF Steering Committee, the GHTF Study Groups, the Singapore Local Organising Committee (comprising staff from the Health Sciences Authority and representatives from the Medical Technology Industry Group of the Singapore Confederation of Industries) and other representatives of the Regional Harmonisation Groups for their support and dedicated efforts in helping to ensure the success of the 9th GHTF Conference and 2nd APEC Seminar.

GHTF Members now look forward to working very closely with the next GHTF Chair and Vice-Chair from Japan. While officially assuming the roles on 1 July 2002 (for the next 18 months), Japan's first major activity will be the hosting of the 5th Meeting of the GHTF Steering Committee.

Further information, including all speaker presentations from both, the 9th GHTF Conference and the 2nd APEC Seminar, and a selection of conference photographs are now available on the "Conferences" page of the GHTF website, <http://www.gh tf.org>

Conference Report 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