



Global Harmonization Task Force

***Rita Maclachlan* reviews the activities and progress
of the GHTF over the last 18 months.**

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Global Harmonization Task Force

Rita Maclachlan reviews the activities and progress of the GHTF over the last 18 months.

The Global Harmonization Task Force (GHTF) is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. It comprises representatives from five founding members grouped into three geographic regions: Europe, Asia-Pacific (Australia and Japan) and North America (USA and Canada). The GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices. The GHTF provides a forum in which official representatives of national regulatory bodies, working with medical device manufacturers and other organisations possessing relevant expertise, can harmonise global approaches to regulating the safety, clinical performance and quality of medical devices in ways that protect public health, promote technological innovation and facilitate international trade. The purpose of the GHTF is to encourage convergence in regulatory practices relating to these issues.

The Chair of the GHTF rotates between the national regulatory authorities of the three geographic regions every three years. The GHTF Vice Chair is appointed from the regulated industry of the same country or region as the current Chair. During the 6th GHTF conference, it was first decided that the Chair would be transferred from Europe to North America for three years commencing in February 1998 (with the USA and Canada each undertaking the role of GHTF Chair for an 18 month period). In January 2001, chairmanship rotated to the Asia-Pacific and Australia (represented by the Therapeutic Goods Administration, TGA) assumed the Chair for the following 18 month period. Mr Terry Slater, TGA National Manager and Ms Rita Maclachlan, GHTF Chair and Director, TGA Medical Devices Program represented the TGA on the GHTF; Mr Brian Vale, Chief Executive Officer of the Medical Industry Association of Australia, held the position of GHTF Vice Chair.

This article focuses on the main business activities of the GHTF during Australia's period as Chair over the past 18 months.

GHTF is a voluntary agency/industry forum seeking convergence of regulatory practices

Hand-over of GHTF chair from Australia to Japan is appropriate point to take stock

GHTF business activities and achievements 2001–2002

The main business activities of the GHTF during the past 18 months have included:

- implementation of the GHTF's governance arrangements;
- GHTF strategic review;
- hosting of the 9th GHTF conference;
- GHTF training;
 - 2nd APEC seminar on the harmonisation of medical device regulations;
- continuation of the GHTF Study Group work programmes;
- implementation of the National Competent Authority Report (NCAR) exchange program;
- the global medical devices nomenclature (GMDN) and the GMDN Maintenance Agency Policy Group; and
- consideration of establishing a permanent secretariat for the GHTF.

GHTF governance arrangements

In September 2000, the GHTF membership approved three procedural documents and established a Steering Committee responsible for management oversight and policy setting for the GHTF. The Steering Committee is now the GHTF's governing body and replaces the previous informal body, established under the US FDA's chairmanship and known as the Ad Hoc Procedures Group. Under the GHTF procedural rules, the Steering Committee comprises a maximum of 24 members, consisting of four government regulators and four medical device industry representatives from the three major geographic regions, being North America, Asia-Pacific and Europe. The Steering Committee members are listed in Table 1. Under its Chair, Australia hosted the inaugural meeting of the Steering Committee in Sydney, Australia from 28 February - 2 March 2001. The 2nd, 3rd and 4th meetings have since been held in Brussels, London and Singapore (during June 2001, October 2001 and May 2002). Since its inception, the committee has constructively worked together in pursuit of the GHTF's international harmonisation goals.

GHTF is governed by a 24-member Steering Committee...

Rita Maclachlan is the out-going Chair of the Global Harmonization Task Force Secretariat, c/-Therapeutic Goods Administration, Canberra, Australia.

Table 1. GHTF Steering Committee membership list

Asia-Pacific	North America	Europe
<p>Australia – Government: Rita Maclachlan (Chair) Director Conformity Assessment Branch, TGA Terry Slater National Manager, TGA Craig Davies (Secretary) Conformity Assessment Branch, TGA</p> <p>Australia – Industry: Brian Vale Chief Executive Officer Medical Industry Association of Australia Barry Evers-Buckland Director Regulatory Affairs - AP Becton Dickinson Pty Ltd</p> <p>Japan – Government: Souichi Ikegaya Director Evaluation and Licensing Division Pharmaceutical and Medical Safety Bureau, MHLW Soichiro Isobe Deputy Director Evaluation and Licencing Division Pharmaceutical and Medical Safety Bureau, MHLW</p> <p>Japan – Industry: Masato Yoshida, Vice President JFMDA Kenichi Matsumoto Chairman Sakura Finetechnical Co Ltd</p>	<p>Canada – Government: Roland Rotter Director – Medical Devices Bureau TPD, Health Canada</p> <p>Canada – Industry: Kevin Murray Vice-President Regulatory Affairs Medical Devices Canada (MEDEC)</p> <p>USA – Government: David Feigal Director Center for Devices and Radiological Health, FDA Lillian Gill Acting Deputy Director for Science Center for Devices and Radiological Health, FDA Dennis Baker Associate Commissioner for Regulatory Affairs, FDA</p> <p>USA – Industry: Robert Britain Vice-President Medical Products National Electrical Manufacturers' Association Michael Gropp Vice President Global Regulatory and Public Policy Guidant Europe James Benson Executive Vice President Technology and Regulatory Affairs, AdvaMed</p>	<p>Europe – Government: Cornelis Brekelmans Head of Unit European Commission DG Enterprise/ G/4 - SC 15/3/156 David Jefferys Chief Executive UK Medical Devices Agency Rainer Voelksen Head of Medical Devices Division, Swissmedic Hanz-George Will Head of Division Federal Department for Health, Germany</p> <p>Europe – Industry: Bryan Allman Vice President Quality Assurance, Clinical & Regulatory Affairs Boston Scientific Corporation Europe Roland Gerard Director – Regulatory and Clinical Affairs St Jude Medical Europe Werner Schoenbuehler Director Group Office for Quality Management Siemens AG Carl F Wallroth General Manager International Standards and Regulatory Compliance, Medical Division Dräger Medical AG & Co KGaA</p>

...comprising 4 regulators and 4 industry reps from each of the 3 founding regions

GHTF strategic review

A major initiative of the Steering Committee during the past 18 months has been to undertake a strategic review of the Global Harmonization Task Force, leading to the subsequent development of a five year strategic plan for the GHTF. During the review, the Steering Committee identified the following six key, strategic themes:

- new, emerging technologies;
- acceptance and implementation of GHTF outputs by national regulatory agencies;
- communication;
- GHTF organisation and infrastructure including Study Group work planning, secretariat and membership issues;
- exchanging regulatory information and the acceptance of assessments between regulators; and
- role of the GHTF with evolving regulatory systems, including potential GHTF training initiatives.

The Committee has progressed the development of the GHTF strategic plan by further refining these themes and identifying a number of goals and actions that have been formulated as the core of the plan. In addition, the Committee developed the following GHTF vision statement: *Enhancing the*

health of the public worldwide and facilitating innovation by harmonising the global regulatory environment. To date, the Committee has progressed a strategic directions document to a 'near-final' draft and this was presented during the plenary session of the 9th GHTF conference on 15 May 2002¹. This document will form the basis of the final GHTF strategic plan following further refinement.

Hosting the 9th GHTF conference

The 9th GHTF conference 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 Steering Committee unanimously agreed to re-schedule the 9th conference, preferably at a location in the Asia-Pacific region. Subsequently, Australia's TGA hosted a successful 9th GHTF conference in Singapore from 12-16 May 2002, with the support of Singapore's Health Sciences Authority (HSA). The two agencies also co-hosted an equally successful GHTF training event, the 2nd APEC Seminar on the Harmonisation of Medical Device Regulations on 17-18 May 2002. Both events were heavily attended and the conference was the largest GHTF gathering to date, with 220 delegates representing 29 countries. The APEC seminar was attended by 180 delegates, primarily regulators and industry representatives from countries with developing regulatory systems. The dedicated efforts made by members of the GHTF Steering Committee and Study Groups, representing Australia, Japan, Europe, USA and Canada were a significant factor contributing to the success of the events.

220 delegates from 29 countries attended the 9th GHTF conference in Singapore

The major highlight of the conference was the one and a half day GHTF plenary which included the official welcoming address by Dr Balaji Sadasivan, Singapore's Minister of State (Health and Environment) and individual sessions on new and emerging technologies, the global regulatory model and the total product life cycle (with a focus on post-market surveillance and vigilance).

The keynote address 'From Harmonization to Collaboration' was delivered by Ms Catherine Livingstone, Chairman of the Board of Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO). Ms Livingstone delivered a dynamic insight into the medical devices sector and highlighted the impact that the genomic revolution, nanotechnology, miniaturisation and computing advances will have on the sector. While applauding the move towards harmonisation of the existing regulatory framework, the key question posed by Ms Livingstone:

is 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 in plenary session two on new and emerging technologies which was moderated by Dr David Jefferys, Chief Executive of the UK Medical Devices Agency. A number of government and industry speakers 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 GHTF to take this issue forward. The suggestion is that a timely guidance document be produced by the GHTF rather than requirements being generated independently by national authorities that would then have to be harmonised by GHTF.

Guidance to regulate emerging technologies may arise first from GHTF, not the agencies

Dr Clarence Tan, Chief Executive Officer of the HSA, moderated the third plenary session on the global regulatory model. The session commenced with an overview of the global medical device regulatory model which 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 harmonised GHTF guidance documents into their national regulatory systems. The GHTF has had considerable success over the last decade and 'the scorecard' impressively highlighted this. 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 their new medical devices legislation in March 2002. Nonetheless the USA, Canada, Japan and the EU member states have also made significant progress with the adoption and implementation of the GHTF principles and guidance documents.

The fourth plenary session on the total product life cycle with a focus on post-market surveillance and vigilance, was moderated by Mr Terry Slater, National Manager of the TGA. The session 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, 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 to addressing long term safety issues or problems that may emerge from relatively minor changes in manufacturing. Equally, it was recognised that low risk devices are not without hazards.

The conference also featured regional information sessions on new and emerging regulatory systems in the Asian economies and the region of the Americas. GHTF members were highly impressed by the on-going progress of the economies of the Asian Harmonization Working Party and the significant amount of progress that has been made by the Latin American countries with the adoption of GHTF guidance documents.

Asian Harmonization Working Party has surveyed the level of device regulation in Asia

Delegates attending the Asian Harmonization Working Party (AHWP) information session were advised of a recent survey conducted by the AHWP technical committee that aimed to: obtain input from Asian regulators on their efforts to harmonise the regulation of medical devices with the GHTF recommendations and guidances; and obtain suggestions for possible regional collaboration and training. The key results of the survey indicated that:

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

Delegates attending the Americas information session were advised that under the leadership of the Pan American Health Organisation (PAHO), a regional action plan has been developed to:

- organise 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.

Statistics describe actual regulatory activity for devices in the Americas

Delegates were also advised of the status of regulatory programmes in the Americas region that may be summarised as follows:

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

Delegates to the conference benefited from an exciting and interactive programme that also featured three concurrent workshop sessions on the global medical devices nomenclature (GMDN), evaluation of the draft World Health Organisation (WHO) *Guidelines for the Development of Medical Device Regulations* and the supply of refurbished medical devices. Additionally, there were meetings of the four GHTF Study Groups (*see later*), the 4th meeting of the GHTF Steering Committee, a Chinese information session and for the first time at a GHTF conference, a poster presentation session and exhibition booths set up by the local industry.

The Steering Committee's 4th meeting was convened on 12-13 May 2002 and the minutes are now available on the 'Steering Committee' page of the GHTF website (www.ghtf.org). The 9th conference provided an excellent opportunity to demonstrate the success the GHTF has achieved in the past but more importantly, it demonstrated that there is a strong and clear strategic direction for the future.

GHTF training

The 9th GHTF conference was followed by the 2nd APEC seminar on the harmonisation of medical device regulations. The program featured approximately 20 expert 'trainers' from the GHTF Study Groups, covering the regulatory agencies of Australia, the EU, USA, Canada, Japan and industry experts from these countries. The GHTF Chair, Rita Maclachlan delivered the opening address and this was followed by two days of training in the GHTF guidance documents, addressing the principles and technical requirements of world best practice in medical device regulations. The key areas covered were pre-market requirements for quality, safety and performance of medical devices, post-market monitoring and manufacturer quality assurance systems auditing and design control requirements. The event 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.

GHTF Study Group work programmes

The four GHTF Study Groups have also continued to make significant progress with their substantial work programmes developed in consultation with, and subsequently approved, by the Steering Committee. The Study Groups form the 'engine room' of the GHTF and the work programmes revolve around the development of the harmonised guidance documents. It is the efforts of the Study Groups that assist the GHTF achieve its goals relating to international harmonisation; for example, the primary manner in which the GHTF achieves its purpose is via the publication and dissemination of harmonised guidance documents on basic regulatory practices. Once endorsed as final documents by the Steering Committee, they can then be adopted/implemented by national regulatory authorities. To date, the GHTF has approved 18 final guidance documents addressing the four principal pillars of medical device regulation:

- pre-market review/regulatory requirements;
- device vigilance/post-market surveillance;
- quality system requirements and guidance; *and*
- auditing practices.

All guidance documents are available on the GHTF website and the final documents are listed in Table 2.

The work of GHTF is divided across four study groups...

Table 2. Final GHTF guidance documents

Guidance document	Study Group
Essential Principles of Safety & Performance of Medical Devices	SG 1
Labelling of Medical Devices	SG 1
Role of Standards in the Assessment of Medical Devices	SG 1
Global Medical Devices Competent Authority Report	SG 2
Minimum Data Set for Manufacturer Reports to Competent Authorities	SG 2
Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan	SG 2
Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices	SG 2
Charge and Mission Statement for SG 2	SG 2
Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative	SG 2
Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria	SG 2
Guidance on Quality Systems for the Design & Manufacturing of Medical Devices	SG 3
Design Control Guidance for Medical Device Manufacturers	SG 3
Process Validation Guidance for Medical Manufacturers	SG 3
Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers General Requirements Supplement No 6: Observed Audits of Conformity Assessment Bodies	SG 4
Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements	SG 4
Audit Language Requirements	SG 4
Training Requirements for Auditors	SG 4
Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements - Supplement No. 4 - Compilation of Audit Documentation	SG 4

...whose work culminates in the issue of final GHTF guidance documents...

Study Group 1 compares the operational medical device regulatory systems around the world and based on that comparison isolates the elements or principles that are suitable for harmonisation and those that may present obstacles to uniform regulations. In addition, the group is responsible for developing a standardised format for pre-market submissions and harmonised product labelling requirements.

...which are considered for revision periodically...

Study Group 2 reviews current adverse event reporting, post-market surveillance and other forms of vigilance for medical devices and analyses the different requirements amongst countries with developed device regulatory systems, with a view to harmonising data collection and reporting systems.

Study Group 3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonisation.

Study Group 4 examines quality system auditing practices (initially among the founding members of the GHTF) and develops guidance documents laying out harmonised principles for the medical device auditing process.

During their meetings in Singapore, the Study Groups also gave further consideration to key issues relating to the revision of a number of guidance documents currently under development and these are outlined in Table 3.

Table 3. Matters relating to development or revision of GHTF guidance documents

Study Group 1

- medical devices classification;
- labelling for medical devices, including *in vitro* diagnostic devices (IVDs);
- essential principles for safety and performance of medical devices to incorporate provisions for IVDs and further revision of the guidance document; *and*
- 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 use errors with medical devices;
- universal manufacturer report format; *and*
- 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); *and*
- 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; *and*
- Supplement No xx: Guidance on the development of audit strategies.

...according to specific issues needing to be addressed

National Competent Authority Report Exchange Program

The pilot phase of the National Competent Authority Report (NCAR) Exchange Program commenced in January 1999 and was completed in May 2000. The countries participating in the exchange during this phase were Australia, Canada, Czech Republic, Germany, Japan, Norway, Switzerland, UK and the USA. The purpose of a linked system incorporating adverse event reporting and vigilance and post-market surveillance components is to improve protection of the health and safety of patients, users and others, by reducing the likelihood of repeated similar adverse events. This occurs through the dissemination of information that could be used to prevent the repetition of adverse events or to alleviate the consequences of such repetition.

Following the receipt of an adverse event report submitted by the manufacturer or their authorised representative, national competent authorities (NCA) determine the necessity/urgency of disseminating this information to member NCAs via the National Competent Authority Report Exchange Program. In noting that 73 reports were exchanged during the pilot phase, the Steering Committee regulators have agreed it had been highly beneficial from a public health and safety

NCAR is a means for sharing adverse report information between regulators

perspective and have given 'in-principle' support to proceed towards full implementation of the scheme. The Committee has already considered a proposal for this developed by Study Group 2 (SG2) and raised a number of issues for further consideration, including:

- various sources of incident reports;
- confidentiality of incident reports;
- how to ensure the most appropriate information is released at the most appropriate time; *and*
- criteria for accepting new participants into the scheme and training for these new participants.

Several issues were identified in sharing surveillance reports between regulators

These issues need to be further addressed before full implementation of the system can proceed. SG2 is currently working on a revised proposal for further consideration by the Steering Committee, which awaits progress on this key post-marketing initiative.

Global medical devices nomenclature

The global medical devices nomenclature (GMDN) is the most appropriate nomenclature to provide medical device generic descriptors and also for the purposes of data exchange, vigilance and commercial identification. The GMDN includes approximately 7 000 preferred generic terms, each with a full definition of the general features covered and a further 7 000 synonym terms to cover alternative routes to the main terms and other 'template' or less detailed general headings.

The GHTF recognises the significant achievement that has been made by the CEN-sponsored development of the GMDN system. The nomenclature will be of particular assistance to those countries with developing regulatory systems for medical devices. The GHTF also welcomes the creation of the GMDN Maintenance Agency Policy Group to continue work on the nomenclature. The Policy Group is chaired by Mr Maurice Freeman (also Chair of GHTF Study Group 1) and the GHTF is currently represented on the group by Health Canada. Some regulatory authorities are actively considering implementing the nomenclature and the GHTF encourages other participating regulatory authorities to undertake an evaluation of the GMDN within their own jurisdictions as soon as possible. The Steering Committee urges that these evaluations be undertaken in partnership with the medical devices industry and in a manner that does not create a burden on the industry. The Steering Committee believes the GMDN will be a major contribution to international harmonisation among regulatory agencies, particularly in vigilance and the worldwide registration of products.

Global medical device nomenclature currently has 14 000 terms

GHTF permanent secretariat

The question of whether or not to establish a permanent secretariat for the GHTF has been a long standing, unresolved issue. The Steering Committee is yet to reach a final consensus on the most preferred, permanent model. The secretariat currently rotates with each rotation of the Chair. To date, this system has worked well, but with the growing work programme it is becoming increasingly difficult to move the secretariat every 18 months and still maintain efficiency of operations and a 'corporate knowledge' base. At its 4th meeting, the Steering Committee gave further consideration to five possible options for the GHTF secretariat, including retention of the current model. The committee has agreed to establish a small working group to further investigate the feasibility of establishing a single permanent location for the GHTF secretariat. With the differing options that may be taken, the committee has already identified a number of key issues to be considered, including the location, governance and funding for a permanent secretariat. The working group will report back to a future Steering Committee meeting.

Where to locate a permanent secretariat is one of the issues in going down that path

Other GHTF activities

In addition to these major initiatives, significant progress has also been made on the following GHTF activities during the past 18 months:

- enhancement of working relationships with the regional harmonisation groups from Asia and the Americas;
- consideration of GHTF training initiatives, with Steering Committee and Study Group members continuing to contribute to various training events around the world;
- monitoring the adoption of final GHTF guidance documents by each of the founding members;
- addressing a proposed merger between Study Groups 3 and 4; *and*
- consideration of a proposal for the GHTF to establish closer collaboration with the World Health Organisation (WHO).

Some jurisdictions have begun actively implementing GHTF guidance documents

Looking to the future

The past 18 months has been a period of accomplishments and has also seen the GHTF consolidate its previous achievements of developing a globally harmonised regulatory system for medical devices and implementing formal procedures for its on-going governance. Having developed the major pillars of the global model, the main challenge now is for the broad GHTF membership to start actively implementing the GHTF principles and final guidance documents in their national regulatory systems. This has commenced in some jurisdictions, but a significant amount of work is yet to be done before it is possible to truly say the global regulatory model has been implemented. The Steering Committee is also very keen to see the interest already demonstrated by the regional harmonisation groups continue. There has been significant progress made, with clear commitment being shown to the adoption of GHTF principles by countries with regulatory systems under development. All GHTF participants need to continue working together at both, the national and international levels in order to achieve the aims of further developing and implementing the global model in ways which harmonise the world's regulatory systems.

Rotation of the GHTF chair to Japan

The GHTF Chair and secretariat officially rotated to Japan's Ministry for Health, Labor and Welfare (MHLW) 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). The hand-over of the GHTF Chair and secretariat commenced in July 2002 and transition meetings involving the TGA, MHLW and JFMDA were held in Tokyo during the first week of August. It is anticipated the rotation will be complete by the time of the 5th Steering Committee meeting, which will be convened in Tokyo under Japan's chairmanship on 28-30 October 2002.

Next key meeting is of the Steering Committee, 28-30 October 2002

Conclusion

It has been the TGA's pleasure and privilege to Chair this important global forum on behalf of Australia and the Asia-Pacific region. Whilst challenging, Australia's chairmanship of the GHTF has been a period of excitement and one of intense activity. The GHTF continues to evolve and has made many significant achievements in harmonising the international regulatory requirements for medical devices since its inception in 1992. It is the TGA's hope that the work done during Australia's term as Chair will provide a number of new outcomes and achievements for the GHTF that will allow for its continued growth and evolution into the future.

The TGA extends its sincere thanks to all members of the GHTF Steering Committee, the GHTF Study Groups and the regional harmonisation groups for their support and dedicated efforts in working cooperatively towards achieving the goals of the GHTF. The GHTF is an excellent demonstration of regulators and industry working together for the benefit of public health. All 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 may be obtained from the GHTF website at <http://www.ghtf.org> or from the out-going GHTF Secretary, Mr Craig Davies, tel: +61 2 6232 8666, fax: +61 2 6232 8687 or e-mail: craig.davies@health.gov.au.

Full GHTF documentation is available on their comprehensive website

References

1. GHTF Strategic Directions (draft), May 2002, available on website <http://www.ghtf.org>, see 'GHTF Conferences'