

**SPECIAL NOTICE**

**Rotation of the GHTF Chair and Secretariat from Australia to Japan**

**Summary Report of Transition Meetings**

**Background**

Currently, the GHTF Chair is shared jointly in the Asia-Pacific region by Australia and Japan. Australia's Therapeutic Goods Administration (TGA) held the Chair from 1 January 2001 - 30 June 2002. Japan's Ministry for Health, Labor and Welfare (MHLW) assumed the role of Chair on 1 July 2002 for the following 18 months.

From 5 - 9 August 2002, meetings to effect the transition of the GHTF Chair and Secretariat from the TGA to the MHLW were held in Tokyo, Japan.

These meetings involved Ms Rita Maclachlan and Mr Craig Davies (outgoing GHTF Chair and Secretary), Mr Souichi Ikegaya (incoming GHTF Chair), Mr Kenichi Matsumoto (incoming GHTF Vice-Chair), Mr Shigetaka Miura (incoming GHTF Secretary), Ms Yoshiko Yamamoto (incoming GHTF Assistant Secretary) and other officials from the MHLW, the Japan Federation of Medical Device Manufacturers (JFMDA) and Quintiles Transnational Japan.

The transition meetings focused on the roles, responsibilities and general business undertaken by the GHTF Chair and Secretary, with particular emphasis on the running and agenda of the GHTF Steering Committee, the work of the GHTF Study Groups and hosting of GHTF Conferences. The agendas for the "Chair's Transition" and "Secretariat Transition" Meetings are at Attachments 1 and 2 respectively. Discussions also covered the following major topics at the appropriate points in time:

**1. Meetings of the GHTF Steering Committee**

The first four meetings of the Steering Committee were held during Australia's period as GHTF Chair. The hosting of the 5<sup>th</sup> meeting will be Japan's first major activity as GHTF Chair. Issues discussed included the draft agenda, on-going action items/matters arising from previous meetings, a timeline for meeting preparation, participation during meetings, recording of meetings, process for preparing and circulating draft and final Minutes, progressing meeting action items and setting dates for future meetings.

**2. 10<sup>th</sup> GHTF Conference**

Japan will host the 10<sup>th</sup> GHTF Conference in Tokyo during May 2003 and a draft Conference program was discussed and will be subject to approval by the Steering Committee during its 5<sup>th</sup> Meeting. Based on Australia's experience with the 9<sup>th</sup> GHTF Conference, other issues discussed included the budget, planning of different meetings and sessions, fees, cancellation policy, banking, financial accountability, logistics planning, registration process (electronic, via the website and on paper forms), the GHTF database as a registration check tool, hotel accommodation, attendees from countries for which Japan requires an entry visa, etc.

### **3. GHTF Strategic Directions: 2002 - 2007**

This is an on-going work item to be further considered and finalised by the Steering Committee. The transition meetings discussed Japan's ideas for progressing this issue, including a proposed re-write of the existing document and development of an action plan which measures progress against the goals and tasks during the next 5 five years.

### **4. GHTF Website**

Issues discussed included the ongoing management and responsibility for the site, a turn-over date (from Australia to Japan), procedures for posting documents, notices after meetings, a separate area for Steering Committee business, website e-mails, renewal of the domain name and website hosting contract, etc.

### **5. Finances**

The TGA's budget and costs for the 9<sup>th</sup> Conference were discussed along with an explanation of expenses incurred by the TGA during its period as GHTF Chair. Australia's approach to seeking and receiving financial support for the Conference was also discussed.

### **6. Memorandum of Understanding (MoU) with ISO/TC 210**

The history behind the ISO/TC 210 - GHTF MoU and the on-going co-operative activities were explained, including an invitation to the GHTF Chair to attend a meeting of the ISO/TC 210 Chair's Advisory Group<sup>(\*)</sup>. In particular, the ongoing collaboration between ISO/TC 210 Working Group #1 and GHTF Study Group 3 was also discussed.

(\*) The next meeting of the Chair's Advisory Group (and TC 210 Plenary) will be held in Berlin, Germany from 12 -13 September 2002.

### **7. GHTF Procedural Documents**

The history, significance and importance of the three, GHTF Procedural Documents were discussed in detail. The documents came into operation following approval during the 8<sup>th</sup> GHTF Conference in Ottawa (September 2000). It was noted that the GHTF has previously agreed that the documents will not be subject to review until after the first three years of operation.

### **8. GHTF Guidance Documents**

Progression of the GHTF Guidance Documents from "Working Draft" to "Proposed Document" to "Final Document" status was discussed in detail. The procedural document, "GHTF Operating Procedures" outlines the requirements and procedures for consultation on the guidance documents and their subsequent advancement.

## 9. GHTF Document Template & Style Guide

Issues discussed included transfer of a diskette containing the template (.dot file), user's guide, implementation amongst the Study Groups, role of the Secretariat in ensuring that the principles laid out in the Style Guide are followed (eg. reinforcement of the document numbering system in the "GHTF Operating Procedures" document, use of the correct cover page, insertion of the GHTF's copyright statement on final documents, etc), and an electronic signature file for use on documents signed off by the GHTF Chair.

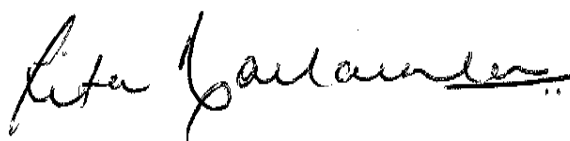
## 10. GHTF Steering Committee and Study Groups - General Business

The transition meetings discussed the importance of maintaining the Steering Committee and Study Group membership lists; liaising with, and assisting Steering Committee and Study Group members; and timelines for responding to e-mails and documents received for further action.

## 11. Other items discussed during the transition meetings included:

- the GHTF Database;
- GHTF Correspondence;
- the approved GHTF PowerPoint templates;
- the GHTF Logo; and
- the GHTF Files and their transfer to Japan.

Meeting summary prepared by Mr Craig Davies, (Out-going) GHTF Secretary, Australia.



Rita Maclachlan  
(Out-going) GHTF Chair; and  
Director  
Conformity Assessment Branch  
Therapeutic Goods Administration  
Australia



Craig A Davies  
(Out-going) GHTF Secretary  
Conformity Assessment Branch  
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**GHTF CHAIR'S TRANSITION MEETING**

**MHLW Meeting Rooms: No. 18 (Monday) / No. 6 (Tuesday)**

**5 - 6 August 2002**

**Agenda**

1. Introduction
  - 1.1 Welcome
  - 1.2 Adoption of Agenda
2. Responsibility and Business of Chair and Vice Chair
3. Preparation for the 5th Steering Committee Meeting
  - 3.1 Agenda of the 5th Steering Committee Meeting
  - 3.2 Program of the 10th GHTF Conference
4. Strategic Direction 2002 – 2007
  - 4.1 Re-write of the document
  - 4.2 Action Plan for Strategic Direction: 2002 – 2007
5. Time Schedule for GHTF Activities
6. Other Business

**GHTF SECRETARIAT TRANSITION MEETING**

**Quintiles Transnational Japan: Meeting Room No. 203**

**7 - 9 August 2002**

**Agenda**

1. Introduction
2. Role and Responsibility of Secretary/Job Description
3. Follow up of Action Items Review at the August 5 Meeting
4. Action Items of Secretary for each Study Group
5. Other Action Items/Pending Issues of Secretary
6. GHTF Document/Information
  - 6.1 Format/Style
  - 6.2 Document Control
7. GHTF Stationary
8. Existing Written Documents of GHTF
9. GHTF Website Management
10. Other Business