GLOBAL HARMONISATION TASK FORCE (GHTF)

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TGA THERAPEUTIC GOODS ADMINISTRATION

INTRODUCTION

• **January 2001 -** Australia (represented by the Therapeutic Goods Administration) assumed the Chair of the Global Harmonisation Taskforce (GHTF) from Health Canada, in line with the rotational arrangements made between the 5 Founding Members.

• Ms Rita Maclachlan, Director of the TGA's Conformity Assessment Branch is the current GHTF Chair.

• The CEO of the Medical Industry Association of Australia (MIAA), Mr Brian Vale holds the position of GHTF Vice-Chair.

PRESENTATION OVERVIEW

• Global Harmonisation Task Force (GHTF)

- What is the GHTF?
- What does the GHTF do?
- What is the purpose of the GHTF & how is this achieved?
- GHTF Study Groups & Guidance Documents
- Recent Activities
- The Immediate Future

WHAT IS THE GLOBAL HARMONISATION TASKFORCE (GHTF)?

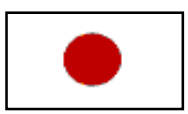
The GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices.

The five founding members of the GHTF are:

Canada

United States of America

European Union



Japan

Australia

WHAT DOES THE GHTF DO?

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 &
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.

ALSO

The GHTF serves as a learning-and-exchange forum in which other countries with existing medical device regulatory systems (or systems under development) can profit from; and pattern their practices upon the experiences of principal GHTF members in order to minimise global proliferation of disparate regulatory requirements.

HOW DOES THE GHTF ACHIEVE ITS PURPOSE?

- Via the publication and dissemination of harmonised Guidance Documents on basic regulatory practices.

- These Guidance Documents are developed by the four GHTF Study Groups -

SG1 - Regulatory Requirements / Premarket Review
SG2 - Device Vigilance / Postmarket Surveillance
SG3 - Quality System Requirements and Guidance
SG4 - Auditing

FINAL GHTF GUIDANCE DOCUMENTS

Once endorsed by the GHTF, the final documents can then be adopted/implemented by member national control authorities.

To date, the GHTF has finalised 16 Guidance Documents.

Australia intends to adopt these Guidance Documents (where appropriate) into the amended Therapeutic Goods Regulations (or as ‘Guidelines’) for use under the new regulatory system for medical devices.

Approved Guidance Documents

Study Group 1

- Essential Principles of Safety & Performance of Medical Devices
- Labelling for Medical Devices
- Role of Standards in the Assessment of Medical Devices

Study Group 2

- Comparison of the Device Adverse Report Systems in the USA, Europe, Canada, Australia and Japan
-Minimum Data Set for M'facturer Reports to Competent Authority
- Guidance on how to handle information concerning Vigilance Reporting related to Medical Devices
- Global Medical Devices Vigilance Report
- Charge and Mission Statement
- Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative

Study Group 3

- Guidance on Quality Systems for the Design and Manufacture of Medical Devices
- Design Control Guidance for Medical Device Manufacturers
- Process Validation Guidance for Medical Device Manufacturers

Study Group 4

- Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers -
  - Part 1: General Requirements
  - Supplement No.3: Training Requirements for Auditors:2000
  - Supplement No.6: Observed Audits of Conformity Assessment Bodies
- Audit Language Requirements

FURTHER EXAMPLES OF GHTF STUDY GROUP ACTIVITIES

Study Group 1 - Summary Technical Files

• SG1 has produced a **draft** document entitled, “Summary Technical File (STF) for Premarket Documentation of Conformity with Requirements for Medical Devices”.

• The purpose of the document is to indicate the content and format for a globally harmonised STF to be used primarily for premarket conformity assessment purposes.

• The STF may be used to provide a ‘roadmap’ to the more complete Technical Documentation for a medical device.

• The contents of an STF are derived from the technical information held by the manufacturer; and compiled in accordance with quality systems and premarket regulations or guidance.

• A number of Australian sponsors and their manufacturers are keen to participate in the pilot study the TGA is currently conducting and have held discussions about submitting dossiers for evaluation.

• The US FDA is also keen to commence a pilot study and is currently consulting with relevant stakeholders on this.

Study Group 2 - Global Vigilance Exchange System

• The GHTF Founding Members, via SG2 initiated a pilot scheme of the Global Vigilance Exchange System. The pilot has now concluded.

• The participating regulatory authorities found the system to be significantly beneficial in reporting serious, worldwide adverse events about medical devices; and have essentially continued to provide reports on an informal basis.

• The GHTF Steering Committee regulators agreed the pilot scheme has been highly beneficial from a public health and safety perspective and has recently given 'in-principle' support to proceed towards full implementation of the scheme.

RECENT GHTF ACTIVITIES

8th Conference - Ottawa, Canada: 18-22 September 2000

- Approval of the GHTF Procedural Documents - Guiding Principles, Operating Procedures, Roles & Responsibilities

- Agreement to establish a new supervisory Steering Committee responsible for management oversight and policy setting.

- The new procedural system also includes a plan for document management, requiring all proposed work projects to be approved by the Steering Committee.

- Agreement to undertake a Strategic Review.

Other Accomplishments from the 8th Conference

SG1 (premarket issues) agreed to set up a pilot program on a standard summary technical file.

SG2 (vigilance) completed work to define information to be included in reports acceptable to every Competent Authority.

SG3 (quality systems) worked on possible wording changes to the final draft of ISO 13485:1996, *Quality Systems: Medical Devices - Particular Requirements for the Application of ISO 9001*.

SG4 (auditing issues)were unable to resolve European concerns about audit length.

GHTF - CURRENT ACTIVITIES

- **January 2001 -** Australia (TGA) assumed the GHTF Chair

- Australia's key GHTF project - to initiate a Strategic Review of the organisation.

- February/March 2001 - TGA hosted the inaugural meeting of the GHTF Steering Committee in Sydney, which was addressed by Senator Grant Tambling.

- June 2001 - The Steering Committee convened its second meeting in Brussels.

STEERING COMMITTEE MEMBERSHIP

- 8 members from the 3 main geographic regions

  - North America (USA and Canada);
  - Asia/Pacific (Australia and Japan); and
  - Europe

- 4 regulators and 4 industry representatives may be nominated from each region.

GHTF - THE IMMEDIATE FUTURE

- 11-16 October 2001 - 9th GHTF Conference, to be hosted by Australia in Barcelona, Spain.

The Conference includes the 3rd Steering Committee Meeting which will give consideration to a number of on-going issues, including a DRAFT Strategic Plan.

- March/April 2002 - GHTF Training Program & 4th Meeting of the Steering Committee in Australia **(to be confirmed)**.

- July 2002 - GHTF Chair rotates to the Ministry of Health, Labor and Welfare, Japan.

9th GHTF CONFERENCE

• In addition to Steering Committee meeting, the Conference program includes meetings of the 4 Study Groups, a Plenary Session and Regional Group Meetings -

- Asian Harmonisation Working Party;

- a Chinese Information Session; and

- a Latin American regional meeting.

• The Plenary Session informs participants of on-going GHTF activities and serves as a forum for participants to discuss pertinent issues or present material that may be of interest to their international colleagues.

CONFERENCE REGISTRATION

Delegates may still register for the 9th GHTF Conference via the following website -

www.gmdconference.com

FURTHER INFORMATION

Visit the GHTF's website at -

www.ghtf.org