



GLOBAL HARMONIZATION TASK FORCE (GHTF)

Rita Maclachlan

GHTF Chair; and

Director

Medical Devices Program

Therapeutic Goods Administration, Australia

2nd APEC Seminar on the Harmonization of Medical Device Regulations

17 - 18 May 2002 - Singapore



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 Medical Devices Program 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 and Accomplishments
 - 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 18 Guidance Documents (2 approved as “Final” at recent Steering Committee meeting).

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 Documentation

- SG1 has produced a **draft** document entitled, “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)”
- The purpose of the document is to indicate the content and format for a globally harmonised STED to be used primarily for premarket conformity assessment purposes.
- The STED may be used to provide a ‘roadmap’ to the more complete Technical Documentation for a medical device.

- The contents of a STED 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. To date, the TGA has received three 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.
- The Committee has recently given ‘in-principle’ support to proceed towards full implementation of the scheme.



RECENT ACTIVITIES & ACCOMPLISHMENTS

GHTF Steering Committee

- **September 2000** - establishment of a new GHTF governing body responsible for management oversight and policy setting.
- The Steering Committee comprises 8 Members from each of 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 Strategic Directions

January 2001 - Steering Committee initiated the Strategic Review and identified the following, six key themes -

- 1) New and emerging technologies
- 2) Acceptance and implementation of GHTF outputs by national regulatory agencies
- 3) Communication
- 4) GHTF organisation and infrastructure including Study Group work planning, secretariat and membership issues

GHTF Strategic Directions

- 5) Exchanging regulatory information and the acceptance of assessments between regulators
 - 6) The role of the GHTF with evolving regulatory systems including potential GHTF training initiatives.
- Further refinement of these themes lead to the development of the Strategic Directions document.
 - The ‘near-final’ version was presented during the Plenary Session of the 9th GHTF Conference on 15 May 2002.

9th GHTF Conference: 12 - 16 May 2002, Singapore

- Re-scheduled from October 2001
- Conference program included -
 - 4th Steering Committee meeting
 - meetings of the 4 GHTF Study Groups
 - AHWP Information Session;
 - a Chinese Information Session;
 - a Latin American regional meeting;
 - 3 Concurrent Workshops; and
 - a four stage, Plenary Session.

Other Activities and Accomplishments

- Approval of more Study Group harmonised guidance documents as "proposed" and "final documents".
- The enhancement of our working relationships with the regional harmonisation groups from Asia and Central/South America.
- Consideration of GHTF training initiatives, and Steering Committee and Study Group Members have continued to contribute to various training events around the world;
- Monitoring the adoption of final GHTF guidance documents by each of the Founding Members.

Other Activities and Accomplishments cont.

- Review and approval of the current Study Group Work Plans in conjunction with the Chairs of each Group.
- Addressing a proposed merger between Study Groups 3 and 4.
- Consideration of a proposal for the GHTF to establish closer collaboration with the World Health Organisation (WHO).



GHTF - THE IMMEDIATE FUTURE

- Prepare 4th GHTF Steering Committee Minutes and a Report/Proceedings from the 9th GHTF Conference. Once finalised, these documents to be made available on the GHTF website.
- **1 July 2002** - official date for rotation of the GHTF Chair from Australia to Japan.
- **July - September 2002** - transitional period, involving meetings between the TGA & Ministry for Health, Labor and Welfare, Japan
- **September or October 2002** - rotation of GHTF Chair to the MHLW, Japan expected to be complete.



FURTHER INFORMATION

Visit the GHTF's website at -

www.ghtf.org

ANY QUESTIONS?

