

18 November 2002

FIFTH MEETING OF THE GHTF STEERING COMMITTEE

The Global Harmonisation Task Force (GHTF) Steering Committee convened its fifth meeting from 28 to 30 October 2002 in Tokyo.

The Steering Committee, established in September 2000, is currently chaired by Ministry of Health, Labour and Welfare (MHLW) of Japan. This meeting was the first under Japan's chairmanship of the GHTF.

In Tokyo, the Steering Committee completed the GHTF Strategic Direction 2002 - 2007.

The meeting focused on the following major issues to be decided.

1. The GHTF Strategic Direction 2002 – 2007

The Steering Committee agreed upon the following GHTF Vision statement and six goals.

Vision: Enhancing the health of the public worldwide and facilitating innovation by harmonizing the global regulatory environment.

Goal 1: Emerging Regulatory Challenges

- The GHTF will encourage and support the timely identification of opportunities to promote regulatory convergence in addressing regulatory challenges including those of emerging public health risks and new medical technologies.
- The GHTF will implement a process to identify these new risks and technologies in order to achieve regulatory convergence in their management.

Goal 2: Implementing Guidance Documents

- The GHTF will encourage the adoption of timely and clear guidance suitable for implementation in national/regional regulatory systems.

Goal 3: Mutual Acceptance by Regulators

- The GHTF will seek to evolve beyond convergence of regulatory requirements to embrace mutual acceptance of common data submissions, pre-market conformity assessment (including clinical evidence) processes, quality systems, quality systems auditing results, and a broad sharing of post-marketing experience. The objective will be to allow presentation of data that are acceptable in principle to relevant authorities as the basis for meeting regulatory requirements.

Goal 4: Evolving Regulatory Systems

- The GHTF Steering Committee will support and advocate the adoption of the global regulatory model in their own systems and those of other countries/regions.

Goal 5: Communications

- The GHTF Steering Committee will develop, implement and monitor a comprehensive communications strategy.

Goal 6: Organisation/Infrastructure

- GHTF Members will seek to establish an affordable, enduring apparatus for managing and advocating the GHTF business agenda.

Several tasks are assigned for each goal. The GHTF Strategic Direction 2002 - 2007 will be posted on the GHTF website in the near future.

2. Common Data

Related to goal 3 mentioned above, the Steering Committee organized the Ad Hoc Working Group to investigate "common data". The group consists of five Steering Committee Members. They will identify items of "common data", rational for their selection, etc. and will report the results to the Steering Committee.

3. Score Card

Concerning goal 2, the Steering Committee agreed to refer to the FDA format as a template of Score Card. The format was presented at the last GHTF Conference. Using the Score Card, GHTF Founding Members will report their status on the adoption of GHTF guidance for implementation in their national/regional regulatory systems at the next GHTF Conference.

4. The 10th GHTF Conference

The Steering Committee amended the proposed program of the 10th GHTF Conference and approved it. The Conference will be held from 25 to 28 May 2003 in Tokyo. The program of the GHTF plenary session is:

Opening Remarks, Annual Report, Strategic Direction 2002 - 2007, Guest Speech, Report of Each Study Group, Score Card and Industry Overview on Harmonization of Medical Device Regulations, Report of Asian Harmonization Working Party (AHWP), Report of Latin American and Caribbean group, Overview of Study Group 2, Experience with Implementation of GHTF Guidance Documents in Australia, Human Tissue Engineering Regulatory Challenge, and Closing Remarks

5. Study Group Items

1) Study Group 1

The Study Group 1 Work Plan was reported to the Steering Committee.

The Steering Committee agreed to review the amendment of the Study Group 1 Document, "Information Document Concerning the Definition of the Term 'Medical Device' (SG1/N29R11)". The deadline for response from Steering Committee Members will be 30 January 2003.

2) Study Group 2

The Study Group 2 Work Plan was reported to the Steering Committee.

The Steering Committee agreed to review the Study Group 2 Documents listed below:

- Global Medical Devices Competent Authority Report (SG2/N9R11)
- Medical Device Postmarket Vigilance and Surveillance; Timing of Adverse Event Reports (SG2/N33R11)
- Manufacturer's Trend Reporting of Adverse Events (SG2/N36R7)

Steering Committee Members will review these documents as FINAL and send their comments to the Chair by 18 December 2002.

The Steering Committee suggested Study Group 2 to review the document, "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program (SG2/N38R10)" at the next Study Group 2 meeting.

The Steering Committee recommended Study Group 2 to integrate SG2/N21 and SG2/N36.

3) Study Group 3

On behalf of Ms. Trautman, the Study Group 3 Chair, the GHTF Secretary reported the brief minutes of the joint meeting between GHTF SG3 and ISO/TC 210/WG 1 from 9 to 12 September 2002 in Berlin, Germany. There were sufficient votes from Member Bodies on ISO/DIS 13485 to advance to the document to the FDIS stage. After review of the compilation of comments, members agreed on the best path forward. The second working draft of ISO/TR 14969, the guidance document for ISO 13485, will be circulated for comments after the meeting. The Study Group 3 Work Plan was reported to the Steering Committee.

4) Study Group 4

On behalf of Dr. Frankenberger, the Study Group 4 Chair, the Secretary reported the minutes of the Study Group 4 meeting on 16 and 17 September 2002 in Luebeck, Germany. Study Group 4 completed the structure of the guidance document on "Regulatory Auditing Strategy".

6. Reports from the Regional Harmonisation Groups

The report from Dr. Tan, the Chair of AHWP, was introduced. The AHWP meeting was held in conjunction with the 9th GHTF Conference on 14 May 2002 in Singapore. The meeting reported on high consensus from Asian regulators on their acceptance or adoption of various Final GHTF guidance documents for their regulatory framework. The next AHWP Technical Committee meeting is scheduled for 12 - 13 December 2002 in Bangkok, Thailand. Major items will be the development of a common submission dossier for manufacturers preparing a pre-market application and using Summary Technical Documentation (STED).

Latin American and Caribbean Group will report its activities at the next Steering Committee meeting.

7. Matters Arising from Previous Meetings

1) Global Medical Devices Nomenclature (GMDN)

Mr. Freeman reported the present status of the GMDN. It is available for licensed users. Those who wish to utilise the nomenclature should visit the information website - "www.gmdn.info". The data file has been updated by the Maintenance Agency Expert Group. The data file is available on a CD-ROM. It was proposed to introduce hierarchical structure to the GMDN.

2) Proposed Memorandum of Understanding (MoU) between the GHTF and World Health Organisation (WHO)

Ms. Maclachlan, the former GHTF Chair, reported the status. The MoU issue has not been resolved yet. It was decided to discuss the issue at the next Steering Committee meeting with Mr. Verollet of the WHO.

3) Regulation of Medical Devices Containing Human Tissue

Each regulator of the Steering Committee reported its regulatory status on Human Tissue issues.

4) European Confederation of Medical Suppliers Association (EUCOMED) Global Standards Strategy Discussion Document

EUCOMED brought up the issue about the relation among the GHTF, ISO and IEC. The Steering Committee did not reach consensus.

8. Timetable for Future GHTF Meetings

The 6th Steering Committee meeting will be convened during the 10th GHTF Conference in Tokyo, which will be held from 25 to 28 May 2003. The Conference will be immediately followed by the 10th Global Medical Devices Conference.

The Steering Committee decided to hold the 7th Steering Committee meeting on the west coast of the USA from 5 to 7 November 2003.

Further details will be posted on the GHTF website - "www.ghtf.org".

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