



GLOBAL HARMONIZATION TASK FORCE

ANNUAL REPORT: 2002 - 2003

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Opening Remarks

Japan's term of the GHTF Chair and Secretariat was very tough and exciting due to the outbreak of Iraq war and SARS as well as essential issues raised in terms of GHTF activities. However, many of the raised and pending issues were resolved owing to great contributions and cooperation of the Steering Committee (SC) members, Study Group (SG) Chairs and SG members. Moreover, a direction for further evolvement of the GHTF was clarified.

1. Japan's Term of GHTF Chair and Secretariat

Japan assumed the GHTF Chair and Secretariat from Australia officially from July 1, 2002 until December 31, 2003. Dr. Taisuke Hojo from the Ministry of Health, Labour and Welfare of Japan acted as the GHTF Chair, and Mr. Kenichi Matsumoto from the Japan Federation of Medical Devices Associations acted as the GHTF Vice Chair. Mr. Shigetaka Miura and Ms. Yoshiko Yamamoto supported them as the GHTF Secretariat.

2. Meeting Held during Japan's Term of GHTF Chair

Two SC meetings were held under Japan's chairmanship. The GHTF Conference, SC meeting and SG meetings, which were scheduled to be held on May 25 to 28, 2003, were cancelled due to the outbreak of SARS. Efforts such as prior distribution of discussion papers and exchange of comments among members were made to avoid delay and lapse of discussion due to the cancellation. Annex A shows the dates and places of meetings of the SC and SGs.

3. Business Activities/Achievements

3.1. Deliverables

3.1.1. The GHTF Strategic Direction 2002 – 2007

The SC agreed upon the following GHTF Vision statement and six goals at the 5th SC meeting held in October 2002 in Tokyo.

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 SC 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 SC 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 has been posted on the GHTF website. Great progress has been observed in many of the tasks. Japan has submitted a status report on the GHTF Strategic Direction 2002 - 2007.

3.1.2. Common Data

Mutual acceptance of common data by regulatory authorities is incorporated in goal 3 of the Strategic Directions as mentioned above.

An ad hoc working group for this project was organized by five SC members including Mr. Will as a leader. The members had a meeting to discuss common data on November 26, 2002 in Berlin. Mr. Will summarized their discussions and reported them. In his report, common data were categorized into five groups: i.e., (1) quality system data, (2) preclinical and other clinical data, (3) documents to demonstrate conformity with the essential principles, (4) vigilance data, and (5) other data. Each category was accompanied with concrete example and prioritized.

Issues related to common data are diverse. Japan proposed that (1) clinical investigation and (2) confidence building should be addressed in the first step. Japan also emphasized necessity to select international consensus standards. The SC agreed to organize an ad hoc working group for clinical investigation, and Mr. Gropp was appointed as the leader. The group will clarify the objectives and scope of this project and report them to the SC at the next SC meeting. Further, the SC decided to assign SG4 to review exchange of quality system auditing results (report). It was decided as well to clarify common data already assigned or to be assigned to existing SGs and data to be assigned to a new SG.

3.1.3. New Direction for GHTF Activities

It was indicated that harmonization of matters directly related to each country's jurisdiction is extremely difficult. Some members suggested that convergence, being less binding, should be targeted instead of harmonization. The EU emphasized "light touch". The SC agreed not to address issues directly related to the jurisdiction or, if such issues are addressed, to focus on principles. It was agreed that detailed and concrete matters will be issued as informative reference. Japan proposed categorization of GHTF documents into (1) documents for harmonization and/or convergence, (2) informative references, and (3) combination of (1) and (2). No consensus was reached on the issue. However, the idea of clarifying the nature of each GHTF document was supported and is reflected in the consensus on new work item proposals and GHTF documents mentioned later.

3.1.4. GHTF Documents Advanced to Next Stage

The following GHTF documents were approved to be advanced to a next stage during Japan's term as GHTF Chair. The next stage to move forward to is stated in parentheses: PD stands for Proposed Document, and FD stands for Final Document.

SG1:

- SG1/N011R17(PD): Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- SG1/N015R21(PD): Principles of Medical Devices Classification
- SG1/N029R13(PD): Information Document Concerning the Definition of the Term "Medical Device"
- SG1/N041R6(PD): Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)
- SG1/N044R4(PD): Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)

SG2

- SG2/N9R11(FD): Global Medical Device Competent Authority Report
- SG2/N31R8(FD): Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative

- SG2/N32R5(FD): Medical Device Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports
- SG2/N33R11(FD): Medical Device Postmarket Vigilance and Surveillance; Timing of Adverse Event Reports
- SG2/N36R7(FD): Manufacturers Trend Reporting of Adverse Events

SG3

- SG3/N99-10(FD): Process Validation Guidance
- SG3N15R6(PD): Risk Management as an Integral Part of the Quality Management System

SG4

- SG4/N30R6(PD): Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

Annex B shows the status of GHTF documents publicly available on the GHTF website as of December 31, 2003.

3.1.5. New Work Item Proposals Approved

The following new work item proposals were approved at the 6th SC meeting held in November 2003 in San Francisco, USA.

SG2

- guidance for adverse event reporting
- guidance on recall/advisory notices

SG4

- supplements to and revision of the guidelines for regulatory auditing of quality management systems

3.2. Achievements Related to GHTF Operation

3.2.1. Improvement in New Work Item Proposals and GHTF Documents

The SC agreed that new work item proposals and GHTF documents should include the background, objective, rationale to justify the proposal or document, and scope. This will be applied to GHTF documents to be developed hereafter. It is intended that the validation and approval by the SC at an early stage prevent waste of time and resources if a project is cancelled or drastically modified after a considerable amount of time spent.

3.2.2. Minutes of SC Meetings

The GHTF Operating Procedures provides that a meeting record should be made publicly available on the GHTF website. A definition of "record" is not given. On the other hand, it is provided that a meeting summary of each Study Group meeting should be posted on the GHTF website. Since the SC meeting is a closed one, the SC decided to post a summary of its meeting on the GHTF website. Detailed minutes will not be disclosed in conformity with the SGs' practice. The summaries of SC meetings had been posted on the GHTF website.

3.2.3. Improvement on SC Meetings

It was proposed at the 5th SC meeting that the duration of SC meetings be shortened. On the other hand, the meeting scheduled to be held in May 2003 in Tokyo was cancelled as mentioned earlier, and we had only two opportunities for SC meetings during Japan's term as the GHTF Chair. In order to make up for the loss, some countermeasures were taken successfully and effectively: i.e., (1) the Chair's proposals and detailed reference materials concerning the agenda were distributed in advance, (2) opinions on the agenda were converged by feedback from SC members on the distributed materials, and (3) meeting attendees were requested to submit written proposals to the meeting with the background, rationale and objectives clearly defined in order to avoid bytalk. Most of issues raised were resolved, and the duration of the 6th SC meeting was largely shortened.

3.2.4. Permanent Secretariat

The GHTF Secretariat had conventionally rotated with the GHTF Chair. The roles of the GHTF Secretariat include (1) support of the GHTF Chair and (2) document control and management of the GHTF website. The FDA proposed that it undertake the latter permanently and bear the expenses. This proposal was welcomed and accepted by the SC.

3.2.5. GHTF Training Institute

The establishment of a GHTF training institute had been a pending issue for a long time. The SC decided to cancel this in light of expenses, etc. On the other hand, it was agreed that the GHTF will continue to review and offer GHTF-related training. The SC also agreed that the FDA as Permanent Secretariat will manage documents for training developed by GHTF.

3.3. Collaboration with Other Organization

3.3.1. World Standards Cooperation (WSC)

The GHTF Chair accepted the proposal on partnership with the WSC from the International Organization for Standardization (ISO), and the SC approved it. A workshop of the WSC will be held in Geneva on February 26 and 27, 2004. The EU will participate in it and present GHTF activities on behalf of the GHTF.

3.3.2. World Health Organization

Negotiation regarding the collaboration between the GHTF and WHO was suspended due to the resignation of a person who had been a contact of the WHO on the issue. The SC decided to continue negotiation with his successor.

3.3.3. Asian Harmonization Working Party (AHWP)

Activities of GHTF-related organizations were reported at the SC meetings.

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 2nd AHWP Technical Committee meeting was held in Bangkok on December 12 and 13, 2002. It was attended by 105 participants from People's Republic of China, Hong Kong, India, Indonesia, Korea, Malaysia, Philippines, Singapore, Chinese Taipei and Thailand, as well as observers from Australia, Belgium and Japan. The major agenda was a common approach to submission requirements in the application to place medical devices on the Asian markets. The project will involve the development of a common submission dossier for pre-market application based on the Summary Technical Documentation (STED). Some members of Study Group 1 supported the meeting.

The 10th AHWP regional meeting was cancelled due to SARS outbreak. Accordingly, election of new office bearers to the next 3-year term of office was also cancelled, and posts of the Chair and Co-Chair of the AHWP as well as the Chair and Co-Chair of the AHWP Technical Committee remain open.

3.3.4. Latin American and the Caribbean Group - Pan American Health Organization (PAHO)/WHO

The Resolution of the PAHO 42nd Directing Council, issued on September 25, 2002, is in full implementation. It urges the Member States (1) to develop and strengthen their programs for the regulation of medical devices, (2) to promote and support the participation of their regulatory authorities in the GHTF Conference and meetings of GHTF Study Groups, and (3) to promote the use of GHTF documents.

The Colombian Working Party has translated the Final Documents of Study Group 2 into Spanish. Colombia, Panama, Peru, Chile and Mexico are using Study Group documents in the revision and updating of the regulatory framework for medical devices.

The WHO and PAHO attended the International Forum for Promoting Safe and Affordable Medical Technologies in Developing Countries held by the World Bank on May 19 and 20, 2003.

3.4. Others

3.4.1. ISO 13485:2003 and Risk Management

The SC adopted the statement on ISO 13485:2003 proposed by SG3. It encourages countries/regions to use the standard for regulatory purpose. The statement has been posted on the GHTF website. ISO 13485:2003 requires risk management. However, it does not include specific requirements and refers to ISO 14971 as informative reference. The SC decided to develop criteria for regulatory auditing of risk management.

3.4.2. Global Medical Devices Nomenclature (GMDN)

The present status of the GMDN was reported at the 6th SC meeting by Mr. Freeman and Dr. Kessler. The GMDN, already completed, has been implemented or is considered for implementation in many countries, and is contributing to harmonization of the nomenclature of medical devices. It is supported by the European Committee for Standardization (CEN) and organizations of other countries. Issues to be addressed are (1) copyright, (2) translation into national languages, and (3) maintenance. The GHTF is expected to support the Maintenance Agency Policy Group (MAPG) and Expert Advisory Team (EAT), and to pledge endorsement and fiscal support from regulators and industries.

3.4.3. Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE)

Mr. Gerard, who took charge of investigation of the BSE/TSE issues raised at the 5th SC meeting in Tokyo, presented a comparison chart of regulations of GHTF Member regulatory authorities. The SC decided to continue this discussion at the next meeting.

4. Future Tasks

4.1. Review of Three GHTF Fundamental Documents

The three fundamental documents of the GHTF, i.e., "GHTF Guiding Principles", "GHTF Roles and Responsibilities", and "GHTF Operating Procedures" are to be reviewed every three years. Japan will make a list of problems and issues related to these documents and hand it over to the EU, incoming GHTF Chair. The EU will draft revisions of these documents.

4.2. Common Data

The SC will further discuss common data in accordance with a policy and strategy to be proposed by an ad hoc working group with Mr. Gropp as the leader.

4.3. Documentation of SC's Decisions

Formal documents will be issued to endorse decisions made at the 6th SC meeting regarding the new work item proposals and development of GHTF documents.

5. Rotation of GHTF Chair and Secretariat and Future Meetings

The GHTF Chair and Secretariat will be transferred on January 1, 2004 from Japan to the EU. The incoming GHTF Chair will be Mr. Brekelmans of the European Commission (EC), and the incoming Vice Chair, Mr. Wagner of the European Confederation of Medical Suppliers Association (EUCOMED). Mr. Brekelmans announced that future SC meetings are scheduled as follows:

- June 2004 in Paris, France
- May 2005 in Seville, Spain
- November 2005 in London, United Kingdom
- June 2006 in Lubeck, Germany
- November 2006 in Brussels, Belgium

Some members indicated that the interval between the first and second SC meetings to be hosted by the EU may be too long. Mr. Brekelmans suggested that he will be flexible on the issue. As the incoming GHTF Chair, he also presented his idea to hold regional meetings besides the GHTF Conference. The Global Medical Device Conference (GMDC) is scheduled to be held in June 2006.

Closing Remarks

The GHTF has been working towards harmonization of medical device regulations in different countries/regions, while the restriction and limitation of harmonization have been clarified. On the other hand, it has been agreed to address mutual acceptance of common data to speedily provide patients and health care providers with new technologies/products. It is a main objective of the GHTF. The ICH has shown significant achievements through practical approach in terms of the regulation of pharmaceuticals. This new evolution means that GHTF activities have moved into the second stage from the first stage. Japan hopes that the GHTF will further evolve under the chairmanship of the EU.

Dates and Places of GHTF Activities

year	2002						2003												2004
month	July	Aug.	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	Jan.
term of Japan's Chair																			
GHTF Conference																			
SC meeting																			
SG1 meeting																			
SG2 meeting																			
SG3 meeting																			
SG4 meeting																			
transition meeting																			
other GHTF-related events																			

SC: Steering Committee

SG: Study Group

Status of GHTF Documents on GHTF Website (as of December 31, 2003)

SG	Title	Description	Posted Date Reposted Date	Comments by	present stage	next stage	Remarks
SG1	N009R6	Labelling for Medical Devices	2000/03/15 2000/10/23		FD		
SG1	N011R17	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)	2003/12/16	2004/03/16	PD	FD	
SG1	N012R10	Role of Standards in the Assessment of Medical Devices	2000/03/15 2000/10/23		FD		
SG1	N015R22	Principles of Medical Devices Classification	2003/12/16	2004/03/16	PD	FD	
SG1	N020R5	Essential Principles of Safety & Performance of Medical Devices	1999/12/28 2000/10/23		FD		
SG1	N029R13	Information Document Concerning the Definition of the Term "Medical Device"	2003/12/16	2004/03/16	PD	FD	
SG1	N041R6	Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)	2003/12/16	2004/03/16	PD	FD	
SG1	N043R3	Labelling for Medical Devices (including In Vitro Diagnostic Devices)	2002/07/29	2002/10/29	PD	FD	
SG1	N044R4	Role of Standards in the Assessment of Medical Devices (including <i>In Vitro</i> Diagnostic Devices)	2003/12/16	2004/03/16	PD	FD	
SG2	N6R3	Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan	2002/07/12		FD		
SG2	N7R1	Minimum Data Set for Manufacturer Reports to Competent Authority	2001/08/29		FD		
SG2	N8R4	Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices	2000/02/16 2000/10/25		FD		
SG2	N9R11	Global Medical Device Competent Authority Report	2003/03/28		FD		
SG2	N12R9	Precis - GHTF Study Group 2: Vigilance and Postmarket Surveillance	2000/02/16		WD	PD	

SG: Study Group

PD: Proposed Document

FD: Final Document

Annex B

SG	Title	Description	Posted Date Reposted Date	Comments by	present stage	next stage	Remarks
SG2	N16R5	Charge & Mission Statement	2000/02/16 2000/10/25		FD		
SG2	N20R10	Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria	2002/07/12		FD		
SG2	N21R8	Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative	Unknown 2000/10/15		FD		
SG2	N31R8	Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative	2003/12/22		FD		
SG2	N32R5	Medical Device Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports	2003/12/22		FD		
SG2	N33R11	Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports	2003/03/28		FD		
SG2	N36R7	Manufacturer's Trend Reporting of Adverse Events	2003/03/28		FD		
SG3	N99-8	Guidance on Quality Systems for the Design & Manufacturing of Medical Devices	Unknown 2000/10/30		FD		
SG3	N99-9	Design Control Guidance for Medical Device Manufacturers	Unknown 2000/10/30		FD		
SG3	N99-10 (Edition 2)	Quality Management Systems - Process Validation Guidance	2004/01/22		FD		
SG3		SG3 Comments on ISO/DIS 13485 submitted to ISO TC 210 Working Group #1	2002/07/24		WD	PD	
SG3	N15R6	Risk Management as an Integral Part of the Quality Management System	2004/01/22	2004/04/22	PD	FD	
SG4	(00) 3	Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements - Supplement 2)	2000/03/15 2000/10/30		FD		

SG: Study Group

PD: Proposed Document

FD: Final Document

Annex B

SG	Title	Description	Posted Date Reposted Date	Comments by	present stage	next stage	Remarks
SG4	(99) 14	Audit Language Requirements (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements - Supplement 1)	1999/12/30 2000/10/30		FD		
SG4	(99) 28	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements	1999/12/30 2000/10/30		FD		
SG4	N(99) 24R3	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements - Supplement No. 4 - Compilation of Audit Documentation (Clause 5.7)	2002/07/12		FD		
SG4	N26R1:2001	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies	2001/08/10		FD		
SG4	N30R6	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy	2003/11/25	2004/02/25	PD	FD	

SG: Study Group

PD: Proposed Document

FD: Final Document