Summary of 6th Meeting of GHTF Steering Committee

The 6th meeting of the GHTF Steering Committee (SC) was held on November 5 and 6, 2003 in San Francisco.

The present GHTF Chair, Dr. Taisuke Hojo of the Ministry of Health, Labour and Welfare, Japan opened the meeting. It was the second SC meeting hosted by Dr. Hojo.

The SC meeting and GHTF Conference, scheduled to take place from May 25 to 28, 2003 in Tokyo, were cancelled due to the outbreak of SARS. Despite this, fundamental problems and issues raised at the 5th SC meeting and thereafter were resolved within this SC meeting as mentioned later. All of the ten GHTF documents submitted by the four Study Groups were approved to move forward to a next stage. They will be posted on the GHTF website in the future.

Prior to the meeting, proposals to resolve pending issues and meeting materials were distributed to Members for comments. Those comments were circulated to Members for convergence of opinions. Through the prior preparation and the discussion focused on substantial items, the efficiency of the meeting was improved and resulted in a shorter term than scheduled.

1. 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 Study Groups' practice. The minutes of the 5th SC meeting were ratified by the SC. The summary of the 5th SC meeting had been posted on the GHTF website.

2. 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 as GHTF documents. It was agreed that detailed and concrete matters will be issued as informative reference. Dr. Hojo presented proposals based on this concept for 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 below.

Regarding the working process of the SC and Study Groups, the SC agreed that new work item proposals and GHTF documents should clearly define the scope, purpose and rationale in each document. This will be applied to GHTF documents to be developed hereafter. It is intended that the SC's validation and approval of essential matters at an early stage prevents waste of time and resources if a project is cancelled or drastically modified after a considerable amount of time spent.

3. Study Group Matters

The GHTF Chair indicated that some of the GHTF documents do not comply with the GHTF Operating Procedures. He suggested that Study Group Chairs observe the Procedures.

3.1. Study Group 1 (SG1)

Mr. Freeman, SG1 Chair reported on activities of SG1. He also proposed the following five GHTF documents. There were no new work item proposals. The next stage to move forward to is stated in parentheses: PD stands for Proposed Document, and FD stands for Final Document.

- 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)

In respect to SG1/N015R21, some regulator of the SC members indicated that classification of medical devices should be limited to principles and that it is not appropriate to designate a specific class for individual medical device types. The regulator suggested that SG1/N015R21 should be reviewed in parallel with the document on conformity assessment. Despite a proposal to add a cover sheet to include the intention of this document, a small ad hoc group was organized to modify the GHTF document. The SC approved to advance the modified version to the PD stage. It was the sense of the SC that SG1 place a high priority on moving the Conformance Assessment Document ahead since it should be evaluated alongside the Classification Document. Further that the Classification Document should not be advanced to a Final Document until the Conformance Assessment Document had undergone wide review and there was a sense in the SC that both documents will work well together.

3.2. Study Group 2 (SG2)

Mr. Dix, SG2 Chair reported on activities of SG2. He also proposed the following new work items and two GHTF documents.

- New work items: (1) guidance for adverse event reporting, (2) guidance on recall/advisory notices, and (3) guidance on enforcement actions
- 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

The SC agreed that SG2 should reexamine new work item (3). The other items and the two GHTF documents were approved without any modification.

3.3. Study Group 3 (SG3)

Ms. Trautman, SG3 Chair reported on activities of SG3. She also proposed the following two GHTF documents and specific items as below. There were no new work item proposals.

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

Both of these documents were approved to move forward to the stage indicated above. ISO 13485:2003, which is the quality management standard for regulatory purposes, was issued on July 15, 2003. Ms. Trautman proposed a GHTF statement to encourage countries/regions to use the standard for regulatory purpose, and the SC adopted the statement. It will be posted on the GHTF website. She also raised the issue how to manage risk from a regulatory viewpoint. ISO 14971 has been issued as a related international standard. However, it is a voluntary standard, and is not intended for a regulatory purpose. The SC decided to develop criteria for regulatory auditing of risk management as an integral part of the quality management system. SG4 will work on the development.

3.4. Study Group 4 (SG4)

Prof. Frankenberger, SG4 Chair reported on activities of SG4. He also proposed the following new work item and one GHTF document.

- New work item: supplements to and revision of the guidelines for regulatory auditing of quality management systems
- SG4/N30R6(PD): Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

Both of the proposals were approved by the SC without any modification.

4. Common Data

Mutual acceptance of common data by regulatory authorities is incorporated in goal 3 of the Strategic Directions agreed at the 5th SC meeting held in October 2002 in Tokyo. Goal 3 reads:

> 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.

An ad hoc working group for this project was organized by five members of the SC 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. Following Mr. Will's report, each Study Group Chair presented the outcome of discussions at the Study Group meeting.

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 for a Study Group to discuss the issue 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) and to clarify common data already assigned or to be assigned to existing Study Groups and data to be assigned to a new Study Group.

5. 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.

6. 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.

7. 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.

8. 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 prepared by GHTF Study Groups, etc. for training.

9. Collaboration with Other Organizations

9.1. World Health Organization (WHO)

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

9.2. World Standards Cooperation (WSC)

The GHTF Chair reported that he had accepted the proposal on partnership with the WSC from the International Organization for Standardization (ISO) after referring to comments from members of the SC. 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.

9.3. Asian Harmonization Working Party (AHWP)

The GHTF Secretariat presented a report of the AHWP provided by Mr. Wong. 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. The 3rd AHWP Technical Committee meeting, which had been tentatively scheduled to be held in Taipei in November 2003, was also cancelled in light of SARS. It is rescheduled for late February or early March 2004.

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

The GHTF Secretariat presented a report of the Latin American and Caribbean group - PAHO/WHO provided by Mr. Hernandez. 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.

10. Global Medical Devices Nomenclature (GMDN)

Mr. Freeman, SG1 Chair and Dr. Kessler reported the present status of the GMDN. 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.

11. Electronic Labeling

Mr. Wagner proposed that electronic labeling (electronic instruction) should be discussed. It was suggested that the status in each country/region should be investigated and the background, objectives, and scope of the project should be clarified. They will be proposed at the next SC meeting.

12. 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 Lübeck, 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.

The 6th SC meeting clarified the limitation of harmonization while it opened a way to mutual acceptance of clinical data and quality system auditing results, etc. by regulatory authorities. With this outcome, Dr. Hojo, as the GHTF Chair, suggested that GHTF activities have moved into the second stage from the first stage. He also emphasized the importance of common data that could lead to reduction in time and resources of regulators and industries. He expressed his hope that the GHTF will have further evolvement and success referring to the ICH, and thanked all the attendees and those who supported the meeting.

As the Incoming Chair, Mr. Brekelmans congratulated the Japanese Chair and its secretariat for a highly successful meeting, in which a great number of documents were advanced to next stage and major decisions were taken on major issues.