Summary of the 9th GHTF Steering Committee Meeting

The 9th GHTF Steering Committee (SC) meeting was held in London, United Kingdom, on the 9 and the 10 November 2005. It was preceded by separate regulator and industry meetings on the 8 November 2005.

1. Welcome and apologies

Participants were welcomed by Prof. Breckenridge, MHRA, hosting the meeting, who acknowledged the work of GHTF and its Study Groups (SG) and expressed the strong United Kingdom support to GHTF.

Ms. Georgette Lalis (EU) chaired the meeting. She welcomed the participants and invited them to present themselves. Participating were from Europe, Abraao Carvalho, Antonio Lacerda, Jean-Claude Ghislain, Jos Kraus, Matthias Neumann, Maurice Wagner, Werner Schoenbuehler, Carl F Wallroth and Christine Tarrajat; for Australia, Rita Maclachlan, Rainer Voelksen, Brian Vale and Johan Brinch; for the US Larry Kessler, Steven M. Niedelman, David P. Kelly, Janet E. Trunzo, Robert Britain, Michael Gropp; for Japan, Masaaki Tsukano, Shigetaka Miura and Hiroshi Ishikawa; for Canada, Roland Rotter and Stephen Dibert; and the Study Groups Chairs, Horst Frankenberger, Alain Prat, Ginette Michaud, Graeme Harris and Jorge Garcia, as well as for the secretariat Jean Olson and Susanne Höke.

The Chair thanked all SC members that left the SC, Terry Slater, Hans-Georg Will, Brian Allman and Evers Buckland, for their invaluable work and input over the last years.

2. Summary Records from the 8th Steering Committee Meeting

A clarification was requested on point 4 of the Summary Records of the 8th SC meeting. The SC agreed that when in discussions on potential problems of determining industry representation for one of the regions at the last SC meeting reference was made to an "agreement between the parties", the parties were understood to be regulators/government **and** industry. It was also underlined that regulators/government will only be involved if industry of one region cannot agree itself on its representation.

3. GHTF Strategic Directions

The aim of the discussion on the GHTF Strategic Directions was on the one hand to ensure a constant review of the activities of GHTF in relation to its Strategic Directions and on the other to start the reflection process for a review of the Strategic Directions in 2007.

The Chair invited Mr. Gropp to present a paper he had prepared, the thrust of which was supported by the SC.

The SC considered in particular that while GHTF work on the general regulatory framework is well advanced, there will be a growing need to address emerging technologies or other more specific issues in the future. These subjects might not necessarily fit in the framework of existing Study Groups (SG). One example is software, a subject that touches on the responsibility of various SGs and requires specific expertise.

Reflection is needed on how such cross-cutting issues could best be addressed in the future by GHTF. One option could be *ad hoc* groups, here it must be considered if they should generally be answerable to the SC as such, or to SGs. Another possibility to consider is to use the concept of "project managers" that could provide horizontal support and liaise between different SGs or to invite on specific issues experts to prepare discussion papers for the SC. It was also underlined that in case there is a problem to have sufficient "fresh blood" and expertise in SGs, this should rather be addressed within the SG and not by creating new groups.

The SC agreed to entrust a small *ad hoc* group headed by Michael Gropp and composed of Maurice Wagner, Hiroshi Ishikawa, Larry Kessler, Rainer Voelksen and Jean-Claude Ghislain with the task to start reflections on the future GHTF Strategic Directions and to present first ideas to the SC in Lübeck.

4. Study Group's work - Progress reports and documents

4.1. Study Group 1

Ginette Michaud, the Chair of SG 1, presented the progress of SG 1 work and in particular the two documents that were proposed to be endorsed by the SC as proposed documents.

SG1(PD)/N015: Principles of Medical Devices Classification

The Chair gave an overview of the main contents of the document, which will assist manufacturers to allocate their medical device to an appropriate risk class using a set of harmonized principles and is meant to be read in conjunction with the principles of Conformity Assessment for Medical Devices that recommends conformity assessment requirements appropriate to each of the four risk classes. The document does not address IVDs, work on IVDs is ongoing. The Chair informed that there was broad consensus on this document within SG 1.

The SC endorsed the document to be posted on the website as proposed document with a comment period of three months.

SG1(PD)/N040 Principles of Conformity Assessment for Medical Devices

The Chair presented the main contents of the document, which describes the procedures that should apply to each class of device, describes the process by which a Regulatory Authority may confirm that such procedures are properly applied by the manufacturer and describes the declaration of conformity. While the document enjoys overall broad consensus, there is an open issue with type examination. In the SG there are different views, ranging from total exclusion of type examination to offering type examination as an option. The Chair underlined that SG 1 had also searched the input of SG 3, but that at this point there is a need for broader public input.

The SC discussed the issue and agreed on its broad support for quality management systems. In relation to type examination there was broad agreement that this should in any case always be an option only and never mandatory. However, the regions that currently use type examination, Europe and Australia, underlined that they would prefer a reference to this option in the final document.

The SC agreed to endorse the document as proposed and to seek comments for a period of three months with the following remark:

"This document is published after extensive discussion within the Study Group.Before proceeding to a Final Document, SG1 seeks comments on all aspects of its contents. In particular, we would draw attention to the manner in which we have referred to the conformity assessment procedure known as 'type examination' (on Page 14)."

The SC also asked the SG to prepare a document on type examination, which would essentially summarize the pro and contra discussions. The Chair congratulated the former Chair Maurice Freeman and the current Chair for their work in these two important documents.

SG 1 Membership

The Chair of SG 1 explained the need to review the membership of SG 1, which has currently 21 members. The Chair proposes that members should be reconfirmed and is aiming for a membership of four members from each regions, half industry, half regulators, thus a total of twelve. The SC generally supported the idea to review membership and encouraged the Chair to seek SC input in case of problems. The SC also encouraged other SGs to undergo a similar reconfirmation exercise.

The SG 1 Chair also confirmed that the secretary is Alan Kent and announced that a Vice-Chair will be determined.

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4.2. Study Group 2

The Chair of SG 2, Jorge Garcia, presented the work of SG 2 by presenting a map of the existing SG 2 documents. He specifically addressed the three documents proposed to the SC for endorsement.

SG2(PD)/N54R6: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
SG2(PD)/N57R6: Medical Devices: Post Market Surveillance: Content of Field Safety Notices
SG2(PD)/N79R5 Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form

The SC endorsed all three documents to go forward as proposed documents and to be posted on the GHTF website for public comment with a comment period of three months. It encouraged SG 2 in relation to the electronic data exchange not to duplicate ongoing ISO work and to update the very useful map showing interrelation of SG 2 documents.

The SG Chair also presented the upcoming work programme of SG 2 and in particular presented the areas SG 2 will concentrate on, notably the implementation of N38, Maintenance of NCAR, monitoring of the uptake/performance of SG2 Guidance, and the improvement of reporting and exchange mechanisms.

The SG Chair suggested that to carry out this work he envisages SG meetings prior to SC meetings and if necessary ad hoc meetings, thus a reduced number of meetings. The SC agreed with the proposed approach.

4.3. Study Group 3

The Chair of SG 3 presented the current work of SG 3 and in particular the new work item proposed to the SC. The SG has currently 12 members and work on risk management is finalized. Co-operation with SG 4 is ongoing.

New proposed work item: SG3N16R0 "Quality Management System – Guidance on Supplier and Outsourced Processes."

The SC welcomed the initiative for the new work and underlined the need for a clear definition of "manufacturer", as well as the need to coordinate work with SG 2 and SG 4.

The SC endorsed the new work item.

4.4. Study Group 4

The Chair of SG 4, Horst Frankenberger, presented the progress of SG 4 work and in particular the document proposed to the SC. He also gave an overview of the SG 4 membership and encouraged participation of another European regulator (the European Commission Services are coordinating European regulators participation).

SG 4 (PD) N30R16: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

On this document the SC had requested SG 4, together with SG 3, to integrate the subject of risk management into the document N30. The SG Chair requested a shortened comment period until 1 February 2006, in order to be able to propose the document to the SC in Lübeck. To ensure SG 3 input, the SC encourages SG 3 to give comments prior to Taipeh meeting of SG 4 in February 2006.

The SC endorsed the document as proposed document with a shortened comment period until 1 February 2006.

4.5. Study Group 5

The Chair of SG 5, Graeme Harris, presented the progress of SG 5 work. The documents on harmonisation of definitions (SG5(WD)N1R3) and on harmonised guidance on clinical evaluation (SG5(WD)N2R2) are expected to be submitted to the SC as proposed documents for its next meeting. The SC also discussed the question of IVDs and in how far they are covered. The SG Chair informed that they will be addressed in separate documents. The SG Chair further informed the SC of the nomination of Greg LeBlanc as Vice-Chair of SG 5 and welcomed the planned signature of the Memorandum of Understanding between GHTF and ISO/TC 194 WG4, which will allow continuous cooperation between SG 5 and ISO.

5. Future approach on software

Following discussions of the last SC, Larry Kessler presented a status report on software used in medical devices, in their manufacture or in their regulatory profile. While certain aspects of software are covered by international standards, these do not cover all aspects. The SC agreed that this is an important issue and strongly supported that GHTF takes up work on the subject. It was agreed to set up an *ad hoc* group lead by Larry Kessler to develop a description of the scope of work to be carried out and proposals how to best approach them.

6. List of designated standards and work on a GHTF glossary

The SC supported the idea brought forward by Japan to collect, and eventually provide on the GHTF website, information on standards that are designated/harmonized in the

different regions for regulatory purposes. To this end SC members will provide the secretariat with links to their respective published lists, which will then be posted on the website.

The SC also welcomed the idea to work on a GHTF Wordbook and Glossary of terms used in the GHTF guidance documents. SG Chairs reported that in some SGs work on such glossary has already been carried out or started. The SC entrusted Alain Prat, Chair of SG 3, with the task to coordinate work on the GHTF Wordbook and Glossary, by in a first step compiling the information that is already available. To this end each SG is to nominate one contact person and provide the information already available.

7. Planning of the GHTF Conference 2006 – Lübeck

The conference in Lübeck will be the GHTF highlight event for 2006. Carl Wallroth presented the current state of preparation. An exciting and interactive programme has been developed, as well as a very attractive evening programme. Carl Wallroth asked all SC members to publicise the conference and to encourage early registrations. He also encouraged the preparation of posters for the poster session. A third announcement with an updated programme will be posted on the GHTF website and send to all SC members and SC Chairs shortly for further dissemination.

8. Preparation of Open Session

The Chair informed the SC about the guests expected for the Open Session. On cooperation with third countries the SC considered that cooperation with organizations that bundle certain regions, such as the Asian Harmonization Working Party (AHWP) or PAHO, is preferable. It was also agreed that overall countries that participate in certain SG should be encouraged to become formally Participating Members. The SC supported the idea to hold Open Sessions in the future and to consider having the reports of the work on SG in these Open Sessions.

Open Session

In the Open Session the SC was joined by Mr Fahlgren from WHO, Mr. McKinley from ISO and Mr. Datuk Ir.Dr.M.S.Pillay (AHWP Chairman), Zamane Abdul Rahman and Sasikala Devi representing the AHWP.

9. WHO

Mr. Fahlgren presented the work of WHO in general and in particular of the department of essential health technologies in relation to medical devices. He underlined that while WHO is not promoting any particular regulatory system, key points promoted are the assessment before placing on the market, a system of product and manufacturer registration and post-market surveillance and vigilance. WHO also encourages countries to consider regulatory convergence at international level and has in this regard developed

the document "WHO guidance on Medical Device Regulations".

Of specific interest for WHO is whether access to certain kinds of vigilance data could be made easier for developing countries. The Chair of SG 2 informed that while the existing GHTF vigilance exchange system NCAR is a relatively open system, there are some caveats in order to ensure protection of confidential information. Countries that wish to participate, therefore, require training and in some cases there is a need for an individual confidentiality agreement. In this regard the document "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program" (GHTF/SG2/ N38R15:2005) is of particular interest for countries interested in participating. It was also discussed whether in the long term WHO could become a kind of "clearing house" for vigilance data.

Another issue of interest would be cooperation on training, and the SC underlined that GHTF would be very interested in participating in WHO organized training events and to provide speakers.

In conclusion, WHO and GHTF envisage to concentrate on exchanging information on issues of common interest, will keep each other informed and involved in relevant training activities and WHO and SG 2 will be in contact on the possibilities in relation to access to vigilance data.

10. ISO

Mr. McKinley, Deputy Secretary-General of ISO, presented the work of ISO, in particular in the medical device field. He underlined ISO's cooperation with IEC and ITU. On the general importance of standards he drew particular attention to the "World Trade Report 2005" on trade, standards and WTO. ISO's Strategic Plan for 2005 to 2010 underlines the importance of support of standards to regulatory systems. Mr McKinley explained that ISO does not promote any particular regulatory system in relation to medical devices, it has created standards on third party assessment, as well as on manufacturer declaration.

On co-operation between ISO, GHTF and other organizations, Mr McKinley underlined the importance of exchanging information and the activities of the Healthcare Technologies Task Force (HTTF), which brings together WSC organizations, partners, regulators, SDOs, manufacturers, Committees (including GHTF) and which is aiming at strengthening dialogue/foster cooperation, promote visibility of work, incorporate risk management approaches and support work with developing countries (with WHO).

Mr McKinley also drew attention to the development of a guide on how to use standards in regulation by ISO, to which GHTF could contribute by providing examples from the medical device field.

On this occasion Mr McKinley and the Chair signed the Memorandum of Understanding between ISO TC 194 and GHTF. Both sides underlined that such practical cooperation is of utmost importance in the coordination of activities.

11. Update from the Asian Harmonization Working Party (AHWP)

The Chair of the AHWP, Mr. Datuk Ir.Dr.M.S.Pillay, presented the work of the AHWP. AHWP represents Hong Kong, the Philippines, the People's Republic of China, Malaysia, Thailand, Indonesia, Korea, Singapore, Chinese Taipei, India, Vietnam and Brunei Darussalam. AHWP objectives are to forge a common direction for the harmonization of medical device regulation in Asia, to encourage increased understanding on the benefits of harmonization and to facilitate a linkage with the GHTF. Important progress has been made in moving towards the GHTF regulatory system in many of the AHWP countries. Closer cooperation with GHTF is one of the key issues for AHWP and Dr. Pillay expressed AHWP interest to become a GHTF member.

The main areas in which AHWP would welcome support and cooperation with GHTF are the advice and experts in development, strengthening of the existing infrastructure member countries towards harmonisation, assistance and advice the member countries without regulations in development and implementation of the regulations and financial support.

The SC welcomed and expressed its appreciation for AHWPs work and achievements and expressed its interest in close cooperation with AHWP. The Chair explained the possibility to become Liaison Body and invited AHWP to do so. GHTF and AHWP agreed to work closely in particular on training and the upcoming conference in Lübeck was identified as a possibility to develop closer links.

The Chair of SG 4 also offered to hold a training seminar in Taipei on "Regulatory Auditing" in February 2006 after the SG4 meeting, an idea that was welcomed by SC and the AHWP Chair. SC members expressed also their intention to endeavour possibilities for bilateral training and for funding for AHWP members to take part in training events.

12. Cooperation with Participating Members

SC members reported on their bilateral co-operation and training activities.

13. GHTF Training issues

The SC underlined the importance of training to GHTF. The SC considered the possibilities to further develop training material existing at SG level and to also endeavour the possibilities of e-learning, which is already successfully used in some regions. The Lübeck conference will offer a possibility to compile existing material and already prior to that the secretariat will start collecting existing material.

14. Update of Main Developments in Founding Members Regulatory Systems

Founding members gave overviews of the main developments in their regulatory systems.

Canada

Canada pointed in particular to the upcoming regulation of reprocessing of medical devices, a programme to intensify market surveillance in the coming year and on pressure from the Canadian Parliament on more transparency in the context of breast implants. Canada also reported that there are considerations to introduce mandatory vigilance reporting from all health care professionals.

United States

The United States in particular drew attention to the fee modernization act. It also underlined an increased emphasize on post-market monitoring in reaction to a number of recalls. The implementation of GHTF guidance documents in the United States is very advanced, but the United States regret that little use is made of the STED so far. The United States also pointed to the challenges arising from imports of medical devices growing at an exponential rate of 25%.

Japan

Japan reported on the main points of the Pharmaceutical Affaires Law reform, which are the risk classification along with GHTF criteria, assessment by a registered assessment body and marketing approval instead of manufacturing approval. Japan classifies more than 4,000 non-proprietary names into four category, i.e. classes 1 – 4. In the Pharmaceutical Affairs Law, three categories exist, highly controlled medical device (class 3 and 4), controlled medical device (class 2) and general medical device (class 1).

Australia

Australia reported in particular on the process of transition to the new regulatory system for medical devices in Australia, as well as on the legislation on re-manufacture of single-use devices. Australia also informed about the new IVD legislative framework, based on GHTF principles, which is to be implemented for mid-2006 and specifically on the requirements for in-house tests. Australia is in the process of regulating tissues and cellular therapies. Finally, Australia reported on the progress and challenges of the Trans-Tasman regulatory scheme under which the establishment of one single regulatory agency for medical devices is foreseen for 2006.

EU

The EU reported on the ongoing revision of the medial device directives, and in particular pointed to the inclusion of stand-alone software in the definition and the requirements for custom-made devices. The draft will be WTO/TBT notified so that there will be possibility to comment. The EU also pointed to the proposal on the regulation of human tissue engineered products, which largely aligns these products with

pharmaceutical products. Attention was also drawn to the ongoing review of the New Approach, as well as to a recently published Study in the competitiveness of the medical device industry in Europe, which is planned to be followed by a conference next year.

Continuation closed session

15. Upcoming meetings

Programme of North-American Chair

Larry Kessler presented the program of the upcoming North American Chair.

Upcoming APEC meeting

A number of APEC meetings have already been held very successfully with participation of GHTF and various SC members. The SC agreed to support the upcoming APEC training event in Chile and asked the Chair to confirm this in a letter to the APEC organising Committee.

Next GHTF SC meeting

The next SC meeting will be held at the occasion of the GHTF Conference in Lübeck, Germany. The SC meeting will start with separate industry/regulator meetings on the 25 June 2006, and with full SC meeting sessions, including an Open Session, on 26 and 27 June 2006.

The last SC meeting under the European Chair will be held in November 2006 in Brussels, Belgium (envisaged dates are the 28, 29 and 30 November 2006).

16. AOB

Proposed Memorandum of Understanding between IEC and GHTF

The Chair presented the SC a proposal from IEC for a Memorandum of Understanding. The SC supported the idea of enhanced cooperation between IEC and GHTF, but requested the Chair to seek clarification with IEC as to whether the Memorandum of Understanding was the most appropriate way forward.

GHTF Participation in HTTF

The SC strongly supported the active participation in HTTF and asked the Chair to nominate a representative to take part in the HTTF work and to report back to the SC.

Status of GMDN

Larry Kessler reported on the current status of GMDN. GMDN has reached a nearly mature status and is unique in relation to other nomenclature in that there is a definition of the devices and a proper linkage. It is constantly evolving and new terms are requested every day. GMDN will now be available as a user-friendly internet-based application under www.gmdnagency.com

SC members expressed their support for GMDN and encouraged other regions and organizations to also use GMDN. Australia has expressively implemented GMDN in its legislation. Japan has translated the whole version into Japanese.

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