Summary of the 8th GHTF Steering Committee Meeting

The 8th GHTF Steering Committee meeting (SC) was held in the European Commission's Joint Research Centre in Seville, Spain, from 18 to 20 May 2005. It was preceded by separate meetings of regulators and industry on 17 May 2005.

1. Welcome

Mr. Abraao Carvalho (EU) chaired the meeting. He welcomed the participants and invited them to present themselves. Participating were from Europe, Abraao Carvalho, Antonio Lacerda, Jean-Claude Ghislain, Jos Kraus, Hans-Georg Will, Maurice Wagner, Werner Schoenbuehler, Carl F. Wallroth and Bryan Allman; for Australia, Terry Slater, Rita Maclachlan, Brian Vale, and Barry Evers-Buckland; for the US, Dan Schultz, Larry Kessler, Steven M. Niedelman, David P. Kelly, Janet E. Trunzo, Robert Britain, Michael Gropp; for Japan, Hiroshi Yamamoto, Masaaki Tsukano, Shigetaka Miura and Hiroshi Ishikawa; for Canada, Roland Rotter; and the Study Groups Chairs, Horst Frankenberger, Alain Prat, Kim Trautman, Kim Dix, Ginette Michaud, Maurice Freeman and Graeme Harris, as well as for the secretariat Ronda Balham and Susanne Höke.

2. Approval of the agenda

The agenda was approved with the following changes:

It was agreed to add two standing agenda items for future SC meetings, updates of policy developments for each of the Founding Members, and updates of contacts with liaison members (WHO, ISO etc.).

For this SC meeting it was agreed to address the Chairmanship of Study Group (SG) 2, as well as a new work item proposal for SG 3 on outsourcing. However, because no paper had been distributed prior to the SC meeting, no decision would be taken. With regard to SG 5, it was agreed to also discuss the proposed Memorandum of Understanding (MoU) with ISO. It was also announced that the planning for the cooperation between the US and Canada regarding the next Chair 2007-2009 will be presented. Finally –time allowing – it was agreed to address the following issues under AOB: software and how to address it in GHTF, status of GMDN and relations with MEDRA, policy with regard to third countries and STED, and multipurpose auditing.

3. Adoption of the note with conclusion of the 7-8 February 2005 SC meeting

SC members were informed that the outcome of the February meeting in Brussels was documented through the relevant changes that were introduced in the three procedural documents and that no separate note with conclusions was available. It was however agreed to prepare such notes for future meetings.

4. Procedural GHTF documents

The Chair suggested mainly using the SC meeting to discuss substantial comments on the documents. The three documents were formally adopted by consensus after inclusion of the changes mentioned below. The texts were subject to editing by a small group on the 20 May 2005 and the results will be circulated to the SC members.

GHTF Guiding Principles

In order to better reflect the respective responsibilities of industry and regulators, the SC decided to change the current wording with regard to "partnership" using the following wording under point 6.3: "While regulators hold the ultimate responsibility for implementation, it is recognized that successful implementation requires the concerted best efforts of regulators and industry;" and to use the term "international cooperation" in other occasions.

The SC also agreed to underline the non-binding character of GHTF documents, and to reformulate the governing principles making reference to "the guiding spirit of GHTF is one of a global cooperation between regulators and industry to achieve its goals and objectives." It was also agreed to use wording like "promoting" when referring to safety, effectiveness/performance and quality of medical devices. Finally the SC underlined that the Guiding Principles should make reference to the Strategic Directions.

GHTF Roles and Responsibility

The SC agreed that the wording "equivalent" used in relation to regulatory systems may have connotations in other contexts (such as WTO) and that reference should rather be made to "well established regulatory systems".

The SC also discussed the possibility that only industry or only regulators from a non-Founding Member may be interested in becoming a Participating Member. It was agreed that in such situations it will be up to the SC to decide on how to proceed, but to not expressively provide for this case in the procedural documents. It was also proposed to attach a chart showing which type of member can participate in which meeting.

The SC discussed the responsibilities with regard to the nomination of industry representatives in case industry itself would not come to an agreement (which could be the case if there are various industry associations that show interest). The SC underlined that it is first and foremost the responsibility of industry to determine its representation, but that in doing so it should ensure broad representation of industry.

The SC agreed that if a problem should arise with regard to the industry representation for one of the regions, this problem should be resolved between the parties within that region, bearing in mind a broad industry representation.

Another issue discussed was the double membership in the SC and in SGs. While some SC members expressed concerns with regard to potential conflicts of interest, industry in particular expressed the need for this possibility because of limited resources. The SC agreed to address this by adding wording according to which SC members that are also SG members will recuse themselves in the SC meeting when a document of their SG is discussed.

Attention was drawn to the necessity to control the size of SGs and it was clarified that while Participating Members have the right to propose SG members, it is the decision of the SG Chair whether to accept the member based on the criteria set out in the Roles and Responsibilities.

The SC also agreed to introduce wording that will allow a region to not have the Vice-Chair account for the number of industry SC members. Finally, it was proposed to clarify the role of the Permanent Secretariat.

GHTF Operating Procedures

The SC considered the different types of documents that are developed by GHTF and it was proposed to add a chart that would explain the different type of documents, i.e. guidance documents, reference documents, status documents, meeting minutes, summary of meetings, training documents and work plans. The SC agreed that the document management in the different stages as described in the Operational Procedures applies to guidance documents, but not to the other type of documents, unless the SC decides to have them undergo that process too. There was also agreement that minor editorial changes should only require agreement of the GHTF Chair.

The SC agreed that while final guidance documents are posted on the website, the decision as to whether, reference or status documents should be posted on the website should remain a case-by-case decision of the SC. Documents that will not be published are new work items and working drafts; for the other documents it is up to the SC to decide whether, or not, a document is endorsed and posted on the website, and such document will also be referred to as "Final," even if it has not followed the full document management process.

In view of the requirements of some Founding Member to undergo a public consultation of GHTF documents and in view of the large number of comments SGs have to cope with, it was agreed to lengthen the time to evaluate comments to 6 months and to provide for some flexibility in prolonging this timeframe.

As regards the format of documents, SC members underlined that documents should normally be published in PDF, unless this is not appropriate. Any forms and related documents intended for downloading and use of the public may be posted in another format (e.g. document for process validation).

With regard to proposed documents for which the comment period has elapsed, it was agreed that these documents are to remain on the website with a disclaimer for three months after termination of the comment period and will then be transferred to an archive that will be established on the website. On document numbering, agreement was reached that the SG secretariats will give document numbers, not the GHTF secretariat.

On training activities, attention was drawn to the need to inform the Chair of any ongoing activities. It was agreed that any training event claiming to represent GHTF should seek prior consent by the Chair. At the same time, it was recognized that it is in GHTF's interest that its work is promoted as much a possible. To help ensure a coherent presentation, the idea was supported, to develop in the future a training handbook on the GHTF regulatory model. There are some first documents (SG 2) that might be used as a basis, but they will need updating and further work.

It was agreed that a form for new work items is to be drafted and that reference should be made in this context to the ISO NWI proposal format. With regard to the procedural sheet, the SC accepted a simplified form. It was clarified that this form is not expected to be filled out retrospectively, but from now on (thus if a document is now in proposed document stage the form will be filled out from that point on).

Conclusion

The Chair expressed his thanks for the spirit of cooperation show by the SC members and the pragmatic approach that allowed progress on these documents, which are of importance for the future of GHTF.

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

5.1 Study Group 1

Maurice Freeman, the outgoing SG 1 Chair, presented the progress of SG 1 work and in particular the three documents that were submitted to the SC to be endorsed as final documents.

N29R16 - Information Document Concerning the Definition of the Term "Medical Device"

The SG 1 Chair informed that this document, which represents the best compromise that could be reached, has already been used by ISO as a reference. The SC endorsed the document as final document. It will be published on the GHTF website following signature by the Chair.

N43R9 - Labelling for Medical Devices

The SG 1 Chair informed that this document was developed on the basis of an existing document and that its aim is essentially to integrate the IVD aspects. He also drew attention to an outstanding industry comment on content of labelling, the missing definition for "detachable components," and the need to align the definition of "intended use" with document N 54. The SG 1 Chair suggested endorsing the document pending the solution of these three issues. The SC endorsed the document, provided that these questions are settled. The SG 1 Chair will inform the Chair when the document is ready for signature.

The SC also agreed that once the new document is available, the old document will be moved to the archive immediately.

N41R9 - Essential Principles of Safety and Performance of Medical Devices

This is an update of the existing guidance document which now integrates IVDs. The SC endorsed the document as a final document. It was also agreed that the document will be removed from the website once the new one is posted. However, the old document should still be available in the archive on the website, with a reference to the new document ("This document was replaced by …."). It was noted by some members of the SC that while the current wording was acceptable, which makes reference to the spirit of the Helsinki Declaration. The Helsinki Declaration, as such, is not acceptable to all regions.

Other Work

SG 1 work on the document on "Conformity Assessment" is the major task and challenge at the moment. The SG 1 Chair informed that work has advanced well and expressed his hope that the upcoming drafting meeting and the next SG meeting in Washington will further advance the document considerably. Connected to the work on this document, is the work on the "Principles of Medical Device Classification" document, which on request of the SC last June, will not be adopted before the "Conformity Assessment" document. In the document on classification, mainly the definition of the central circulatory system is in discussion. SG 1 is also working on a draft document on the classification of IVDs and is beginning work on premarket conformity assessment of IVDs.

The outgoing SG 1 Chair, Maurice Freeman, thanked all members of SG 1 for their work and terrific support. He wished all the best to Ginette Michaud for her work as incoming SG 1 Chair.

The SC expressed its appreciation for Mr. Freeman's long term dedication to SG 1, as well as his outstanding role in building up GHTF and in representing Europe.

5.2 Study Group 2

The Chair of SG 2 reported on the progress of work of SG 2 and in particular on the progress with regard to the document proposed to be endorsed as a final document.

N38R14 - Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

This document has completed its time on the web and the SG 2 Chair gave an overview of the comments received and how they were addressed. The SC endorsed the document as a final document to be posted on the website following clarification of the table, to show that full participants also receive public information, and replacement of the reference to N 54 in the document with references to final documents.

Attention was drawn to the fact that since the NCAR exchange addresses both, public and confidential information, for the US this exchange will require a separate agreement between FDA and the receiving Competent Authorities. The SC also underlined the need to follow-up on the implementation of the exchange program in the future.

With regard to the practicalities of the training on NCAR, the SG 2 Chair drew attention to the provisions in the document itself, countries will receive training from participating members.

N47R4 - Review of Current Requirements on Postmarket Surveillance

The SG 2 Chair informed that this is a "status document" describing current requirements. The SC endorsed the document as a final document pending comments from Australia.

N61 R5 - PMS Harmonization Chart

The main purpose of this document is to inform the SC of the current status of postmarket surveillance and to decide if any GHTF action – either by SG 2 or by other SGs – is required. The SC requested the SG 2 Chair to seek congruence with regard to the comments section and to possibly develop the scope and rationale further. The document should then be presented to all other SGs to discuss which of the issues raised could be addressed in which SG, allowing SGs to come back with suggestions to the SC in November, which will then decide on the further approach.

N68R3 - Summary of Current Requirements for Where to Send Adverse Event Reports

This is a status document and a summary as to where to send adverse event reports. It was developed after a consensus could not be reached on a guidance document in order to provide an overview of the current situation. The SC endorsed the document as a final document pending comments from Australia.

N72R4 - Proposed New Work Item for SG2-Electronic Data exchange of adverse event reports

The SG 2 Chair presented this new work item to the SC and drew attention to the fact that minor corrections will still be made to the text. While the SC is generally not intending to allocate new work to SG 2, it endorsed this new work item under the provision that it can be addressed most expeditiously by SG 2 and requested the SG 2 Chair to report to the SC in November whether any problems were encountered or are expected, in particular with regard to existing different formats.

Finally, the SG 2 Chair raised the issue of SG 2 Chairmanship. In accordance with the agreement made in Paris in June 2004, the current Chair stayed for one more year, but now would like to step down. SG 2 suggests Jorge Garcia from TGA to take over the Chair as of September 2005. The SG 2 Chair also emphasized that while the work program might be finished there is a need to maintain documents and to meet in order to support the NCAR system (need for at least one meeting per year).

The SC agreed to invite Jorge Garcia to take over the Chair of SG 2 and also emphasized the need to find a new secretariat for SG 2. The SC took note of the request to review the process of nomination of SG Chairs and the functioning of SGs in "maintenance mode". The SC congratulated and thanked the outgoing SG 2 Chair, Kim Dix, for his outstanding work and dedication in the past.

5.3 Study Group 3

The SG 3 Chair presented the progress of work to the SC and in particular the document proposed to be endorsed.

N 15R8 - Implementation of risk management principles and activities within a quality management system

The SC endorsed this document as final and decided to post it on the website, incorporating some editorial comments.

On other work, cooperation with SG 4 on regulatory auditing systems is ongoing, will be continued in Washington and the SG 3 Chair hopes to have a proposed document for the SC London meeting, and, ideally, a final document for the SC in Lübeck.

The SG 3 Chair also presented a new work item on multi-site product realization activities in the context of medical device manufacturers quality management systems. The SC supported the work item in general, but agreed to have it resubmitted to the SC in London for endorsement. It requests the SG 3 Chair to expand on the NWI further (e.g. relation to ISO work).

The SG 3 Chair also raised the issue of old SG 3 documents on the website, which are outdated and overtaken by ISO documents. The SG 3 Chair requested to move these documents to the archive and to add a reference to ISO. The SC 3 Chair will inform the Secretariat and the Permanent Secretariat about the documents in question.

In terms of membership, the SG 3 Chair informs that Andrew Lattimore is a new representative from Australia and that the SG is missing a Japanese representative and would like to have at least a contact person.

The SC thanked the outgoing SG 3 Chair, Kim Trautman, for her excellent work over the last years and welcomes Mr. Alain Prat as incoming SG 3 Chair.

5.4 Study Group 4

The SG 4 Chair reports on the progress of SG 4 work.

N30R14 - Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

The SG 4 Chair presented the above document and drew attention to the fact that, in agreement with SG 3, risk management should be integrated in the document. The SC agreed that it is best to publish the complete document, including risk management, as a final document. It requested SG 3 and SG 4 to accelerate work on this document and - once the risk management part is finalized – to present it to the SC as a proposed document. In the interim, a disclaimer should be added to the existing proposed document drawing attention to the ongoing revision work and providing a timeframe.

The SG 4 Chair also reported on the ongoing work in relation to regulatory audit reports and informed that the SG will aim at presenting a Working Draft in September, but that the need to accelerate work on risk management may make this difficult. The SG 4 Chair was encouraged by the SC to schedule an additional meeting and to concentrate on audit strategy in the next meeting.

The SG 4 Chair also drew attention to the fact that there is no European CA SG member and requested nominations.

5.5 Study Group 5

The SG 5 Chair Graeme Harris presented himself, his experience in TGA and the progress made in SG 5 so far. SG 5 was established in June 2004. The SG 5 Chair presented the terms of reference and informed that SG 5 has a balanced membership in terms of regions and experiences, including, in particular, members with experience in ISO. The first meeting was held in Canberra in January 2005.

The SG 5 Chair presented the SG 5 Work Plan and the SC agreed that work can continue on this basis and that no separate new work item proposals are needed. It also confirmed that the timeframe of 18 months given to the SG commenced only with its first meeting. The SG will concentrate on:

- Harmonisation of definitions
- Harmonised guidance on clinical evaluation
- Harmonised content and format for clinical investigation reports

The SG 5 Chair also proposed to the SC to establish a Memorandum of Understanding (MoU) with ISO/TC 194. Although SG 5 will liaise mainly with ISO/TC 194 WG4, the MoU will be established with ISO/TC 194 to allow other GHTF SGs to interact with ISO/TC 194 and its various technical committees in the area of biological evaluation of medical devices. The SG 5 Chair proposed that SG 5 will contribute to the revision of ISO 14155 'Clinical investigation of medical devices in human subjects' by ISO/TC 194 WG4 through members common to both groups. The groups will also exchange Minutes of meetings and information about new work items, and there is the potential for joint meetings as well.

The SC congratulated SG 5 Chair on the successful kick-off, suggested that they take IVD aspects into account, and to possibly appoint a Vice-Chair and a secretariat.

6. Planning of the GHTF Conference 2006 - Lübeck

Carl Wallroth presented the progress made by the conference planning group so far, and Peter Linders presented the draft conference programme. The SC congratulated both with the preparations and the planning group, thanked Carl Wallroth for the warm welcome in Lübeck and the impressive facilities chosen. The SC agreed to set up a small working group to meet on 20 May 2005 to work on the programme. The results of this group will be circulated to the SC.

The SC then preceded to discus the draft program and other organizational questions:

Organizational Questions:

- The SC emphasized the importance of starting to promote the conference as early as possible and suggested using existing address lists from Canada/Australia as a starting point.
- The SC pointed out that as regards timing, it might be difficult to continue until Friday evening and suggested to rather start on Wednesday. It was also emphasized that it is difficult to have concurrent SG meetings and SC meetings, as it is important for SG Chairs to participate in the SC. A proposed solution was to shorten the SC meeting, have 2 days conference programme, 2 days SG meetings and a 1 day SC meeting.
- As regards the fee the SC agreed on the envisaged fees, but requested that there be no fee for invited speakers that are not GHTF members (euro 300 for industry,

200 for regulators; 50 reduction for advanced registration; 100 for social program participants).

- To facilitate the organization the SC decided that each region should have a key person that will be the contact for the conference and invited each region to provide that contact person to the Chair.

Programme:

- The SC suggested that there is no need for a region by region reporting from regulators or industry, this report could be given for all regions.
- The SC also suggested taking up the issue of emerging technologies and how they can be addressed in global regulatory model.
- It was proposed to include an overview of the GHTF strategic directions, as this was a major issue in Singapore.
- "Dinosaur" idea might be problematic as some newer members might have had more input. Maybe it can be an idea to honour people in form of photographs/slide shows?
- It was also suggested that current regulatory issues would be most attractive to participants and that the workshops should be well integrated in the Plenary, in particular as regards design for patient safety.
- The SC also advised that the conference announcement should clarify that the SG meetings are not open to the public.

Proposed topics for the 4 workshops were:

- Design for patient safety
- Counterfeiting (it was suggested that this is too specific and should rather be broadened to intellectual property)
- STED use of standards in conf. ass.
- Auditing of risk management

The next planning group will be meeting on 23 and 24 June 2005 in Lübeck.

The SC thanked Mr. Wallroth, Mr. Linders and the planning group for all their work.

7. Upcoming meetings

APEC meeting – Bangkok, 13 – 15 June 2005

SC members informed that several of them will be represented in this third APEC Seminar, but drew attention to the fact that as no funding is available for regulators, participation will be a serious problem in the future for GHTF regulators. It was also suggested to discuss the status of this event in connection to GHTF at the next SC meeting.

AGs Joint Meeting – Washington, September 2005

Ronda Balham reported on the practicalities of the Joint SG meeting on 12 to 16 September 2005. Any SC members can receive an invitation and would be hosted by FDA, but should announce as early as possible their participation. The Chair pointed out that this is not a formal meeting of the SC on this occasion.

8. Next GHTF SC meeting

The next meeting of the SC will be held on 7 – 9 of November 2005 (from 1 pm on the 7th to 1 pm on the 9) in the outskirts of London. This coincides with the EU Presidency of the UK and there is therefore no room for manoeuvre in terms of dates. Separate meeting rooms are booked to ensure the industry/regulatory meeting on the 7th in the afternoon. Chair will invite senior UK regulator to participate in the SC meeting.

The SC made the following suggestions for the agenda:

- GHTF Strategic directions,
- Update of policy developments for each of the regions,
- Update of contacts with liaison members (WHO, ISO etc.),
- List of designated standards and glossary,
- Cooperation with ICH,
- Open session to allow PAHO and Asian Harmonization Working Party to report, encourage and seek a written report. Participation would be restricted to this agenda point,
- Training regarding GHTF matters, GHTF institute, presentation materials,
- Request for guidance on "Refurbished devices" and "boundary between medical devices and cosmetics",
- IEC/TC 62 to establish a MoU between GHTF, formal request will be coming up (electrical medical safety standards) and distributed to SC,
- Proposal from Japan for creating a list of designated standards, which all founding member are using in each regulation or guidance,
- Possible initiative on software and the ISO/IEC document on software (IEC 62304).

The Chair announced that a draft agenda will be sent before 1 August 2005.

The SC took note that in view of the date of the joint SG meeting in September 2005 some of the SG documents will only be available 6 weeks before the SC. It was agreed that these documents will be put on the agenda, but that anyone could object to their endorsement or discussion because the 2 months time limit was not respected.

9. AOB

The Chair proposed a short tour de table to allow SC members to update on policy developments in their region:

EU:
The review of the Medical Device Directive is currently up for consultation on the Commission's website until 25 June 2005 (http://europa.eu.int/comm/enterprise/medical_devices/consult.htm) and will then be submitted to the Council and the European Parliament. Ongoing work on vigilance and on clinical evaluation has influenced and is closely related to GHTF work. Legislation on human tissues is under development and the Chair draws attention to ongoing consultation on this issue and invites comments until 20 June 2005 (http://pharmacos.eudra.org/F2/advtherapies/index.htm#pb).

Japan:
The Pharmaceutical Law has become effective in April this year. Major changes include the introduction of GMDN as basic nomenclature in Japan, the introduction of the GHTF classification system, the change of GMP rules to ISO 13485, and the adoption of STED as dossier form.

Canada:
Canada published "summary basis of decisions" on licensed class four devices on the website (modelled after the FDA programme). It might eventually be expanded to refusals. Canada also informs that 15 projects are ongoing as the result of an earlier audit of the medical devices program, including reuse of single use devices (stakeholder consultation), cost recovery (for evaluation), timely access (market access), introducing QM, and basically the whole program is being assessed.

Australia:
Australia adopted the GHTF model in 2002, and is halfway through the implementation (every new device has to comply). Australia is working on human tissues legislation, which will treat them as biologics and work on a risk based approach. A single market will be formed with New Zealand with a single regulator starting July 2006 (New Zealand does not regulate devices currently). Australia also informs that Rainer Voelksen will join TGA for one year.

US:
The US is continuing its critical path initiative to identify scientific problems in relation to market access. A consultation on ideas for research on this issue is ongoing. US expressed its concern to ensure safety of medical devices on the market and to avoid similar situation for devices as occurred in the past for drugs. Human tissues rules are in place, a workshop this summer will aim at developing a risk based approach.

On GHTF document implementation in the US, it is pointed out that for SG 1 the STED could be very helpful. Reviews so far appear positive, but more experience is needed and industry should participate in the pilot. With regard to SG 2 there is major agreement on NCAR, adverse event reporting, work still ongoing on electronic reporting and further

refining is needed. On SG 3 and 4 the US considers that it is time to test the system with multi-purpose inspections, and encourages using the system (pilot studies).

The US informs that David Kelly will be the third SC member (besides Larry Kessler and Steve Niedelman).

Software and how to address it in GHTF

The SC invited regulatory authorities to send information on how software is addressed to Larry Kessler and both secretariats by 4 July 2005 to allow Larry Kessler to prepare a summary report and present that to the next SC in November. A decision can then be taken whether to address this in an ad hoc group or in which other way. Attention is drawn to ISO/IEC document on software (IEC 62304).

Planning for US/CANADA

The planning for the US/Canada Chair was presented and input asked on the planning in summer so that dates can be set in November to allow proper planning.

The Chair closed the meeting thanking all participants for their contributions and announced that the drafting meeting and the meeting on the conference planning will be held in the same room on the following day.

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