Minutes of GHTF SG3, Novotel Apollo, Singapore, May 12, 13 & 14, 2002

Present:

Rex Bean,	Australia
Egan Cobbold,	Canada
Victor Dorman-Smith,	E.U.
Tony Gould,	Australia
Ken Kopesky,	U.S.A.
Yashushi Murayama,	Japan
Alain Prat,	E.U.
Shingtaka Miura,	Japan - May 14 only

Note: John Gams, Canada, sat in the meeting by invitation.

In the absence of Kim Trautman (Convenor, USA), Victor Dorman-Smith acted as Chairperson with Egan Cobbold recording the proposed documentation changes. Proposed changes to DIS 13485 were tabulated by Tony Gould.

The following is a record of the discussions and proposed future actions.

1. Discussed whether to continue work on the draft guidance for quality planning. Consensus was that ISO 9001:2000 plus DIS 13485 requirements for planning were sufficiently explicit that no GHTF guidance would be useful. SG3 considered the draft guidance in WD14969 and amended two paragraphs slightly and decided to send the proposed changes to ISO TC210 WG1 as SG3 contributions.

2. Discussed the SG3 proposal for guidance on the integration of a risk requirement system into a quality management system. SG3 considered the requirement in DIS 13485, clause 7.1 and decided that it was not clear enough. Drafted proposals for two requirements to replace the existing one, one in clause 7.1 and one in clause 7.3.1. It was stated that ISO TC 210 JWG Risk Management was already considering guidance on the integration of risk management into Q.M.S. So SG3 considered postponing any further action on this work item until additional information and coordination was received from the TC 210 JWG. *This item has been revised with respect to drafting the Risk Management Guidance Document since the Singapore meeting. See note below.*

Note: After the SG3's meeting in Singapore, SG#3 chair contacted ISO TC 210 JWG on Risk Management (Alf Dolan, Chair) and found out that there was confusion about their working plan on a guidance document integrating risk management in the Quality Management System. The JWG has no plans to develop such a document and

encouraged GHTF SG#3 to undertake the task. The JWG requested that at least one member of their work group be included in this project for proper collaboration and consultation. Mr. Harvey Rudolf and possibly one other JWG member will work with GHTF SG#3 to initiate drafting the guidance document which was approved by the Steering Committee on several previous occasions.

Initial drafting will occur this fall and a meeting on February 10-12, 2003 in Birmingham, UK is being organized to further this work item.

3. Some concern was expressed by Canada that the provision in DIS 13485, clause 1.2, on possible exclusion of some or all of the subclauses in clause 7 was too liberal and might lead to a non-harmonised approach.

After the Singapore meeting, members worked on drafting the appropriate comment and proposed language with respect to this issue. The comment and proposal was added to the comments on ISO DIS 13485 and submitted to TC 210.

4. Reviewed the GHTF SG3 guidance on Design Control. Revised the references in the document to reflect the different design elements as set out in DIS 13485. Without doing a line-by-line review SG3 listed several points where the document could be improved. It was agreed that each member of the SG would take on section of the document and prepare a revision in time for a 2-day meeting which was proposed for Berlin on September 7 & 8 just before the next ISO TC 210 meeting.

Due to logistical issues, the 2-day meeting in Berlin in connection with the TC 210 meeting is not possible. The Study Group will try to accomplish this task via email. Members have volunteered for specific sections to edit.

All suggested revised text on the Design Control Guidance must be submitted to the SG#3 Chair no later than September 20, 2002. Every member is responsible for revising at least one section. Please contact the chair if you are uncertain as to your assigned section.

5. Reviewed the GHTF guidance document on Process Validation in light of the changed requirements in DIS 13485 (inherited from ISO 9001: 2000) which are considerably more restrictive than those in ISO 13485:1996. While the vast majority of the guidance was still valid, that in Section 3 was out of date and Victor Dorman-Smith undertook to provide a revision to Section 3 of the document by end June for circulation to the SG.

Any suggested revisions to the Process Validation Guidance document must be submitted no later than September 20, 2002.

6. Considered other possible issues for SG3:

Points raised were –

a. Guidance on the validation of the application of computer software in medical devices and in the production processes – an FDA document was mentioned for possible adoption by GHTF.

b. Development of a statement that GHTF could consider for adoption on a harmonized approach to the application of a QMS to manufacturers who may have several production facilities controlled by a head office and those manufacturers using subcontractors.

c. Introduction of an open-ended work item to scrutinize standards on aspects related to QMS for adherence to the principles of GHTF

d. Clarification of our relationship on the drafting of ISO TC 14969

e. Development of a statement on the use of ISO 13485 (as opposed to ISO 9001) as the central focus of a regulatory system for medical devices that GHTF might endorse.

7. Following conclusion of the meeting at 11.45 a.m. on May 14th, most of the SG members agreed to continue with a line-by-line review of DIS 13485 – this continued until 10.00 a.m. on May 15th and provided a detailed list of comments that, after review by all members of SG3, will be submitted to ISO TC 210 for consideration at the Berlin meeting in September.

8. Future meetings –

a. September during the TC 210 meetings in Berlin, date and time TBA depending on TC 210 WG#1 progress.

b. February 10-12, 2003 Birmingham, UK

c. May 2003 in Tokyo at full GHTF meeting.