GHTF SG3 - Quality Systems Minutes of Meeting June 1999

1. Welcome and Introductions

Kim Trautman welcomed members to Washington and the meeting. The first day of the meeting was open to observers and Kim described the nature and purpose of the GHTF and SG3. Members present at the meeting were:

Maria Donawa - Consultant
Victor Dorman-Smith - Abbott
Richard Farb - Baxter
Tony Gould - Therapeutic Goods Administration, Australia
Hirokazu Hasegawa - MHW, Japan
Pierre Landry - Health Canada
Shigetaka Miura - GE Medical Systems
Yasushi Murayama - Olympus Optical
Werner Schönbühler - Siemens Medical
Kim Trautman - Food and Drug Administration
Rainer Voelksen - Swiss Federal Office of Public Health

2. Brief Review of Status of Quality Systems

Representatives of Australia, Canada, Japan, EU and USA gave a brief update as to the status of their quality systems regulations

3. Brief update of MRAs

Representatives from Australia, Canada, EU and USA gave a brief update on the status of their MRAs.

4. ISO TC 210 Status report

Rich Farb reported on the recent meeting of ISO TC 210 WG1. The minutes of the meeting of WG1 were shared and a discussion was held regarding their strategy for the revisions of ISO 9001. It was agreed to support the efforts of TC210 WG1, and a letter was drafted in this regard (note addendum to these minutes).

It was recommended that Kim Trautman and other representatives of regulatory agencies from SG3 be appointed as liaisons to ISO TC 210 WG1.

5. Review of Process Validation Guidance Document

The Process Validation Guidance Document version from February 1999 was reviewed and comments solicited. It was agreed that two minor changes should be made: reference to the requirement that 13845 has for process validation should be removed, and the bullets in the section on planning activities for validation should be synergized with the summary of activities bullets at the end of the document.

6. Proposals for the plenary session of GHTF on 29 June 1999

It was agreed that the three completed documents of SG3 should be proposed as final to the plenary session. These include the guidance on quality systems, design control and process validation. Additionally, it was agreed to seek approval from the plenary for guidance documents regarding quality planning and risk management as applied to medical device quality systems.

7. Plenary session

The plenary of GHTF approved the three documents and the work plans for quality planning and risk management as applied to medical device quality systems.

8. Quality planning

Quality planning concepts were debated. A rough outline and concept document was prepared (GHTF SG3 N99-1). A drafting committee of Maria Donawa, Rich Farb and Tony Gould was assigned to prepare the next draft.

9. Risk management for medical device quality systems

A discussion of the concepts of risk management was held, but no draft document was prepared.

10. Next meetings

The next meeting was set for October 13th and 14th in Paris. Baxter will host the meeting and Rich Farb will send out logistical materials as soon as they are developed. The following meeting is to be held just prior to the ISO TC210 WG1 meeting, which is tentatively scheduled for December in London. The next meeting will be 3, 4 and 5 of May 1999, just prior to the ISO TC210 meeting in Chicago.

11. Public forum

On 1 July SG3 held an open public forum to update interested parties as to the activities of SG3.

ADDENDUM

1 July 1999

Mr. Robert Allen, Chair
ISO TC 210
Quality Management and related requirements for Medical Devices

Dear Mr. Allen,

The Global Harmonization Task Force (GHTF) is chartered to seek harmonization of regulatory requirements for medical devices on a global basis. The GHTF has been largely successful in harmonizing quality system requirements through the

endorsement and utilization of ISO 9001 and ISO 9002 as the recommended system. The regulations in Japan and the United States have been developed and promulgated with ISO 9001 as the core basis, while modifying the language and some details to fit the needs of regulatory processes. Furthermore, Australia and Canada directly call out in their regulations compliance with ISO 13485 or ISO 13488. The European system of third party assessments through the "new approach" directives has directly used ISO 9001 and ISO 9002, with supplemental requirements for application of quality systems. The European model has been and is continuing to be adopted, with the use of ISO 9001 and ISO 9002, in many other parts of the world for regulatory purposes.

Unfortunately the changes to ISO 9001 and ISO 9002 being developed by ISO TC 176 make the new version unsuitable for regulatory purposes. The fundamental emphasis on continual improvement, customer satisfaction, certain concepts of the process model and the reduction in scope concept make the use of the new ISO 9001 unusable as a regulatory tool.

As a result of these developments, we strongly encourage you to proceed with your plans to develop revisions to ISO 13485 and ISO 13488. These revisions should maintain the basic concepts of the 1994 versions of ISO 9001 and ISO 9002, while maintaining the additional requirements for medical devices in the current ISO 13485 and ISO 13488. The revisions should be modeled after the new ISO 9001 format as much as possible, while eliminating those elements that make the new ISO 9001 unsuitable as a regulatory tool.

Instead of allowing reduction in scope as proposed by ISO TC 176, TC 210 should develop both ISO 13485 and ISO 13488 to fit the existing regulatory schemes. This will have the effect of ISO TC 210 performing the reduction in scope for the medical device sector.

We look forward to direct participation in these efforts of ISO TC 210, and the fulfillment of these objectives, which are extremely important to assure safe medical devices that perform as intended.

Sincerely,

Kimberly A. Trautman,
Convener GHTF SG3