Global Harmonization Task Force
Study Group 3

Meeting Summary

July 22-24, 2003
Reston, VA, USA

The GHTF SG 3 met in Reston, Virginia, USA, from July 22nd through 24th, 2003.

In attendance were: Kim Trautman (FDA and Chairperson), Jan Welch (FDA), Erin Keith (FDA), Al Taylor (Acting Chief, Medical Electronics Branch, CDRH), Ed Kimmelman (TC210 WG1 Chair), Dr. Victor Dorman-Smith (EUCOMED), Werner Schoenbuehler (COCIR & Siemens Medical Solutions), Alain Prat (Agence Francaise de Securite Sanitaire des Produits de Sante – Direction de l'inspection et des establissements), Shigetaka Miura (Japan Federation of Medical Devices Associations), Yasushi Murayama (Japan Federation of Medical Devices Associations & TUV Product Service), Joep van Lieshout (European Diagnostic Manufacturers Association), Ken Kopesky (Medtronic), Tony Chan (Guidant Corporation, TC210 JWG) ,and Gunter Frey (National Electrical Manufacturers Association & GE Medical Systems).

The agenda was proposed as follows:

1. Approve the GHTF Statement for ISO 13485:2003 to resubmit to the Steering Committee for Nov. 2003
2. Complete the draft Risk Management/QS Guidance Document in order to submit to the GHTF Steering Committee as a proposed document at their Nov., 2003 meeting.
3. Make sure the Design Control and Process Validation Guidance Revisions are finalized for submission to the Steering Committee
4. Discuss TC176 Product Support Guidance on Outsourcing
5. Other business
6. Next Meeting and proposed dates

1) GHTF Statement for ISO 13485:2003

The statement, as submitted to the members of SG3, read as follows:

Global Harmonization Task Force (GHTF) Statement on ISO 13485:2003

"GHTF considers ISO13485:2003 an acceptable standard for a Medical Device Quality Management System, and does not believe ISO9001 alone is sufficient for medical devices or that ISO9001 should be required in addition to ISO13485:2003."

The statement as proposed reads:

Global Harmonization Task Force (GHTF) Statement on ISO 13485:2003

"GHTF considers ISO13485:2003 *"Medical devices – Quality management systems – Requirements for regulatory purposes"* an adequate standard for a medical device quality management system. For the purpose of regulating medical devices, GHTF believes that:
- the generic ISO9001:2000 is insufficient by itself and
- ISO9001:2000 should not be required in addition to ISO13485:2003.

Countries considering incorporating quality management system requirements directly into their regulation and not citing ISO13485:2003 verbatim are encouraged to harmonize their regulation with ISO13485:2003"

2) DRAFT RISK MANAGEMENT/QS GUIDANCE DOCUMENT

Significant discussion arose around the request from Mr. Shigetaka Miura regarding GHTF position or guidance on the application of risk management requirements in light of current regulatory scheme revisions in various countries.
The group was unsure as to how to influence regulatory authorities or legislation with regard to specific requirements or auditing to risk management requirements. Ken Kopesky and Mr. Shigetaka Miura were asked by the Chair to propose short paragraph for discussion at the Steering Committee meeting in November.

The majority of the meeting was spent working on the draft Risk Management/QS guidance document.

SG3 to complete any and all homework assignments and provide any final comments on the "RISK MANAGEMENT AS AN INTEGRAL PART OF THE QUALITY MANAGEMENT SYSTEM" by August 15th in order to submit to the Steering Committee as a proposed document for the November meeting.

3) FINALIZE REVISIONS TO DESIGN CONTROL AND PROCESS VALIDATION GUIDANCE

Need to review the process validation revisions and provide comment by no later than August 15th, 2003 (COB) to Kimberly Trautman.

Need to arrange for electronic copy of design control guidance document for editorial changes to be consistent with ISO13485:2003.

SG3 must receive guidance from Steering Committee in November on procedures/protocol for revising already finalized documents.

4) DISCUSSION ON TC176 PRODUCT SUPPORT GUIDANCE ON OUTSOURCING

The question was raised as to whether the guidance document on "Outsourced processes" provided by TC176 (ISO/TC 176/SC 2/N 630R) is sufficient and adequately represents the intent of this group as well.

TC176 has provided several guidance documents for implementation of ISO9001:2000 – TC210/WG1 will review these at the WG1/SG3 meeting in September, 2003 (Florence) to determine if additional regulatory guidance would be required. The February, 2004 WG1/SG3 meeting (Sydney) will work on any of these guidance documents to develop sector specific (medical device specific) guidance as deemed necessary/appropriate.

Ed Kimmelman emphasized to the group that any modifications or additions to the 176 document by WG1 or SG3 should be clearly addressing regulatory needs.

Based on the Birmingham meeting review of the "Common Data Set" recommendation, SG3 now recommends to TC210 WG1 that the ISO/TC176/SC2 guidance on "Outsourced processes" (ISO/TC 176/SC 2/N 630R) at a minimum be further developed to address sector specific (medical device specific) issues.

The proposed work item discussed at the Birmingham SG3 meeting will therefore be split between SG3 and TC210 WG1. SG3 will develop a decision tree for regulatory guidance on how to evaluate supplier's conformance to organization's Quality Management System requirements. TC 210 WG1 will undertake sector specific (medical device specific) guidance on the topic of purchasing and outsourcing.

5) OTHER BUSINESS

General regional updates were given.

6)   MEETINGS AND PROPOSED DATES

LOCATION	DATE	WORK ITEMS
Tokyo, Japan	May 25-30, 2003	Risk Management Guidance Draft 2 Final Design and Development Guidance for Re-issuance Final Process Validation Guidance for Re-issuance - CANCELED -
Washington, DC	July, 2003	Risk Management Guidance Proposed Draft for Comment
Florence, Italy ISO TC 210 WG#1/SG3	September 22-25, 2003	Final Drafting of ISO TR 14969
Europe	Nov/Dec 2003	Review public comments and revise Risk Management Guidance Document for Final CANCELED - Timing of publication does not support this schedule (moved to Spring, 2004)
Sydney ISO TC 210 Plenary and WG#1/SG3	February, 2004	Product Support Guidance
Canada (Ottawa?)	Spring 2004 (May/June)	Review public comments and revise "Risk Management Guidance" Document for Final
????	Fall, 2004	Continue Review of public comments and revise "Risk Management Guidance" Document for Final Supplier Evaluation and Verification of Purchased Product Decision Tree – Initial Drafting
Europe GHTF Plenary	May, 2005	Supplier Evaluation and Verification of Purchased Product Decision Tree