Global Harmonization Task Force (GHTF) Study Group 3
Meeting Summary
February 10-12, 2003
Birmingham, UK

The GHTF SG 3 met in Birmingham, UK, from February 10th through 12th, 2003.

In attendance were:

Kim Trautman (Chairperson, FDA),
Jan Welch (FDA),
Dr. Victor Dorman-Smith (EUCOMED, Abbott Ireland),
Dr. Harvey Rudolph (Technical Expert, UL),
Werner Schoenbuehler (Cochir, Siemens),
Alain Prat (Agence Francaise de Securite Sanitaire des Produits de Sante Direction de l'inspection et des stablissements),
Althea Lawrence (Medical Devices Canada, Becton Dickinson Canada),
Shigetaka Miura (Japan Federation of Medical Devices Associations,GE Medical Systems),
Yasushi Murayama (Japan Federation of Medical Devices Associations, TUV Product Service),
Joep van Lieshout (European Diagnositc Manufacturers Association, bioMerieux bv),
Ken Kopeski (AdvaMed, Medtronic), and
Gunter Frey (National Electrical Manufacturers Association, GE Medical Systems).

The agenda was proposed as follows:

1. General
2. Steering Committee Assignment
   - Common data set study group comments
   - revision to work item document on website
   - identification of documents to be forwarded to Steering Committee in May
3. Work on risk management guidance document
4. Review comments received on two existing GHTF SG# 3ocuments
5. Determine meeting schedule for next 18 months

1) GENERAL

- The Chair proposed the nomination of a Secretary for SG3 – no nominations or volunteers were received. The Chair will continue to perform both duties but still asserted that a permanent secretary was desired.

- An overview of the last Steering Committee Meeting in Tokyo, Japan in October 2002.
  - GHTF endorsements were subject of discussion, with it being unclear how "endorsement" should be interpreted.

- FDIS ISO13485 is expected to be published on February 13th, with a 2 month voting period.

- Japan is expected to adopt 13485 2003 version, yet the base laws of the Japanese regulations may require some differences (not expected to be major),

- Canada has already expressed it's position of adopting the document,

- FDA is very much aligned with the current version,

- EU did not go out as a parallel vote for CEN/CENELEC, meaning that the harmonized EN version of this standard will be available with some delay (Unique Acceptance Procedure could be applied to the FDIS, which would limit the delay to approx. 3 months). France indicated that there are 4 negative votes to the proposed ISO13485 (Germany, Switzerland, Austria, and France). Based on feedback from the European members, it can reasonably be foreseen that some, if not all, of these negative votes will turn to "in favor".

☑ SG3 to draft a statement of support for ISO 13485:2003 as a harmonized approach to quality system requirements to submit to the Steering Committee for approval and posting on the GHTF website.

PROPOSED GHTF STATEMENT ON THE USE OF ISO 13485

ISO 13485:2003 "Medical devices – Quality management systems – Medical devices – System requirements for regulatory purposes" is an international standard and was written by ISO TC 210 Working Group 1 in conjunction with GHTF Study Group 3.

ISO13485:2003 is based on ISO9001:2000 however a few requirements have been modified and several medical device particular requirements have been added that have been deemed necessary for regulatory purposes.

GHTF considers ISO13485:2003 an acceptable standard for a Medical Device Quality Management System, and does not believe ISO 9001 alone is sufficient for medical devices or that ISO 9001 should not be required in addition to ISO 13485.

Those countries considering incorporating quality management system requirements directly into their regulation and do not cite ISO13485:2003 verbatim are encouraged to harmonize their regulation with ISO13485:2003.

2) STEERING COMMITTEE ASSIGNMENT

➢ Discussed the November 26, 2002 Meeting of the Ad hoc-Group "Common Data"

Background:

In its 5th meeting on 28th - 30th October 2002 in Tokyo the GHTF Steering Committee intensely discussed the goals and the future strategy of GHTF. One of the most important strategic goals is global acceptance of regulatory data. In that context an Ad hoc-Group was set up to further think

about global acceptance of data and to identify possible future work items of GHTF, which could contribute to achieving this goal. Mr. Will was asked to chair the Ad hoc-Group, to convene a meeting and to report the outcome of the deliberations to the GHTF Secretariat by end of December 2002 (see attached files)


"Dr. Hojo's Meeting Report Common Dat


"Dr. Hojo's Meeting Report Common Data

SG 3 reviewed and discussed responsibilities for the SG3 "data sets" identified in Dr. Hojo's Meeting Minutes of the ad hoc-Group meeting November 26 in Berlin. SG3 discussion and decisions are captured below:

Common Data Set		
Responsible Party	**Issue**	**SG3 Decision**
SG3	**Risk Management:**	Already an approved work item and work in progress
SG3	**Supplier Evaluation and Verification of Purchased Product** As a new work item, it was suggested that SG3 could develop an analysis of the different venues/manufacturing sites where quality system compliance needs to be assessed - decision tree.	Propose New Work Item for Supplier Evaluation and Verification of Purchased Product
SG3	**Internal Audits:** SG3 to consider internal auditing when developing guidance on supplier evaluation and verification of purchased products based on a principle decision tree .	Could be partially addressed in the Proposed New Work Item for Supplier Evaluation and Verification of Purchased Product
SG3	**Design Verification and Validation:** This is considered completed work at this time.	Work already completed. SG3-N99-9
SG3	**Non-Conforming Product:** Nonconforming product requirements and concepts are a part of Corrective and Preventive Actions (CAPA). SG3 will evaluate the guidance in TC 210's ISO TR 14969 which is Guidance on ISO 13485:2003 and then determine if CAPA guidance is needed on top of TR 14696	Not considered necessary at this time but will reevaluated after the publishing of TC 210's ISO TR 14969
SG3	**Process Verification and Validation:** This is considered completed work at this time.	Work already completed. SG3-N99-10
SG3	**Design History File; Device Master Record; Device History File:** While these are all FDA terms, similar documents are required, this appears to be clearly understood within industry and it is consensus of the Study Group that this does not fall within the scope of work for this group	Not considered necessary at this time

SG3	**Internal Complaint Handling Procedures:** This requires further clarification, but in general this is considered part of CAPA. To be further assessed at a later time.	Not considered necessary at this time but will reevaluated after the publishing of TC 210's ISO TR 14969
SG3	**Records of Corrective and Preventive Actions – CAPA** SG3 will evaluate the guidance in TC 210's ISO TR 14969 which is Guidance on ISO 13485:2003 and then determine if CAPA guidance is needed on top of TR 14696	Not considered necessary at this time but will reevaluated after the publishing of TC 210's ISO TR 14969

- Additional Work Item Proposals from the Singapore meeting of May, 2002 were reviewed:

  - Guidance on the validation of the application of computer software in medical devices and in the production processes: Two documents were offered as possible sources, the FDA document that GHTF SG3 reviewed and commented on back in Ireland in 2000 (http://www.fda.gov/cdrh/comp/guidance/938.pdf) was mentioned as a possible adoption by GHTF as well as new work being developed in ISO CD17667 (N213). Chair to provide to SG3 members electronic copy of ISO CD 17667.

- ☐ Members to review ISO CD 17667 and determine if the next round of this ISO standard should receive formal GHTF SG#3 comments. Bring decision to Tokyo meeting. If so, SG#3 will review the DIS and the Chair will collate comments and send to IEC (Nick Tongson).

  - Introduction of an open ended work item to scrutinize standards on aspects related to QMS for adherence the principles of GHTF. A new work item was not deemed necessary but there was a commitment that all felt this was a part of the study groups standing operating principles.

  - Clarification of our relationship on the drafting of ISO TC 14969 (Guidance document to ISO13485:2003). It was reconfirmed that SG3 continues to be formally invited to participate with TC210 on this draft.

  - Explore posting of the GHTF SG#3 statements on ISO 13485 (as opposed to ISO9001) as the central focus of a harmonized regulatory quality system for medical devices.

- ☐ Victor Dorman-Smith to review the website to determine if "Recommendations for Emerging Regulatory Systems" can be posted there.

- Identification of Document to be Forwarded to Steering Committee

	type	title	description
Editorial Revisions of previous Final Documents for accuracy with new ISO standards	Final Document	SG3-N99-9	Design Control Guidance for Medical Device Ma
Same as above	Final Document	SG3-N99-10	Process Validation Guidance for Medical Device
	Please fill in below.		

3) RISK MANAGEMENT IN THE CONTEXT OF QUALITY MANAGEMENT

Risk Management requirements have many linkages to Quality Systems and vice a versa – this guidance document is to identify and establish those linkages. SG#3 plans on using ISO 13485 and ISO 14971 as the basis for the guidance document, but not directly reference any requirements. The guidance document will be based in principles. Several Risk Management reference documents were provided by the Chair to the Study Group in advance and were only intended to facilitate discussion.

RISK MANAGEMENT AS AN INTEGRAL PART OF A QUALITY SYSTEM

- Introduction
  1. Purpose
  2. Scope
- Definitions
- General/Documentation
- Management Responsibilities
  1. Policy
  2. Planning
  3. Resources
  4. Oversight
  5. Approvals
- Design and Development
  1. Risk Analysis
     a) Hazard Identification
     b) Risk Estimation
  2. Risk Evaluation
  3. Risk Control
  4. Acceptability of Residual Risk
- Product Traceability/Identification
- Purchasing Controls and Acceptance Activities

- Production and Process Controls
    1. Process Validation
    2. Work Environment
    3. MFG Equipment Preventive Maintenance
- Servicing
- CAPA
    1. Post Production Information (Post Market Surveillance, Post Marketing Studies, Servicing, Service records, Complaints, , etc.)
    2. Manufacturing non-conformities/defects, Engineering Non-conformities/defects
    3. Quality System/Internal audit findings
    4. Quality System/External audit findings
- Design Changes (Product and Process)
- Statistical Techniques

A draft guidance document was prepared.

- Study group members were given assignments for drafting and reviewing. All drafting assignments and comments on the document due to the Chair by April 30th.

4) DESIGN CONTROL AND PROCESS VALIDATION GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS

Study Group worked on revisions to the existing GHTF Design Control and GHTF Process Validation Guidance Documents. It was decided that editorial revisions would not be made but only revisions in order to ensure guidance consistency with the revised requirements in ISO 13485:2003.

- Proposed revision plans for the revision of these GHTF Final Documents will be submitted to the Steering Committee by March 24th for re-issuance as Final Documents (FD).

5) Upcoming Meeting Schedule

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
Washington, DC	August, 2003	Risk Management Guidance Proposed Draft for Comment Supplier Evaluation and Verification of Purchased Product Decision Tree – Initial Drafting
Florence, Italy ISO TC 210 WG#1	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
Canada	Spring 2004	Supplier Evaluation Decision Tree