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 10\textsuperscript{th} through 12\textsuperscript{th}, 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 stabilisatements),
- 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 Diagnostic 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# 30cuments
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 13\textsuperscript{th}, 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)

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:

<table>
<thead>
<tr>
<th>Common Data Set</th>
<th>Responsible Party</th>
<th>Issue</th>
<th>SG3 Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SG3</td>
<td>Risk Management:</td>
<td>Already an approved work item and work in progress</td>
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<tr>
<td></td>
<td>SG3</td>
<td>Supplier Evaluation and Verification of Purchased Product</td>
<td>Propose New Work Item for Supplier Evaluation and Verification of Purchased Product</td>
</tr>
<tr>
<td></td>
<td>SG3</td>
<td>Internal Audits:</td>
<td>Could be partially addressed in the Proposed New Work Item for Supplier Evaluation and Verification of Purchased Product</td>
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<tr>
<td></td>
<td>SG3</td>
<td>Design Verification and Validation:</td>
<td>Work already completed. SG3-99-9</td>
</tr>
<tr>
<td></td>
<td>SG3</td>
<td>Non-Conforming Product:</td>
<td>Not considered necessary at this time but will be reevaluated after the publishing of TC 210’s ISO TR 14969</td>
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<tr>
<td></td>
<td>SG3</td>
<td>Process Verification and Validation:</td>
<td>Work already completed. SG3-N99-10</td>
</tr>
<tr>
<td></td>
<td>SG3</td>
<td>Design History File; Device Master Record; Device History File:</td>
<td>Not considered necessary at this time</td>
</tr>
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*“Dr. Hojo’s Meeting Report Common Dat”*
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
3) RISK MANAGEMENT IN THE CONTEXT OF QUALITY MANAGEMENT

Risk Management requirements have many linkages to Quality Systems and vice 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
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

<table>
<thead>
<tr>
<th>LOCATION</th>
<th>DATE</th>
<th>WORK ITEMS</th>
</tr>
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<tbody>
<tr>
<td>Tokyo, Japan</td>
<td>May 25-30, 2003</td>
<td>Risk Management Guidance Draft 2</td>
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<tr>
<td></td>
<td></td>
<td>Final Design and Development Guidance for Re-issuance</td>
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<td></td>
<td></td>
<td>Final Process Validation Guidance for Re-issuance</td>
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<tr>
<td>Washington, DC</td>
<td>August, 2003</td>
<td>Risk Management Guidance Proposed Draft for Comment</td>
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<td>Supplier Evaluation and Verification of Purchased Product</td>
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<td></td>
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<td>Decision Tree – Initial Drafting</td>
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<td>Florence, Italy</td>
<td>September 22-25,</td>
<td>Final Drafting of ISO TR 14969</td>
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<tr>
<td>ISO TC 210</td>
<td>2003</td>
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<td>WG#1</td>
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<tr>
<td>Europe</td>
<td>Nov/Dec 2003</td>
<td>Review public comments and revise Risk Management Guidance</td>
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<td>Document for Final</td>
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<tr>
<td>Canada</td>
<td>Spring 2004</td>
<td>Supplier Evaluation Decision Tree</td>
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