Global Harmonisation Task Force, GHTF, Study Group 4: Auditing
Meeting on 16 / 17 September 2002 in Luebeck, Germany

Action points

Meeting dates:
16 September 2002 from 10.00 h to 18.30 h
17 September 2002 from 08.30 h to 17.00 h

Chair: Prof. Dr. Horst Frankenberger, EUROM VI, Europe (Germany)

Structure of the guidance document „regulatory auditing strategy“
(only for “regulatory auditing strategy”!)
The following actions shall be taken by the named members:
1. Introduction (Horst, Reviewer Markus)
2. Scope (Horst, Reviewer Markus)
The scope of this guidance applies to initial audits and surveillance audits as
they are defined in “Guidelines for Regulatory Auditing of Quality Systems of
Medical Devices Manufacturers - Part 1: General Requirements” (SG4 /
N28R2) developed by GHTF Study Group 4 as a guide for auditors.
3. References (all members)
4. Definitions (all members)
5. General Part: (Horst, Reviewer Markus)
Remarks on Regulatory Auditing
Regulatory Auditing and
Regulatory Auditing Strategy

Dates:
Author to Reviewer:                      Latest 10 December 2002
Author / Reviewer to Secretariat:  Latest 20 January 2003

6. Specific Part
Three columns as below (Johann will inform David on the given structure and
the reason why we have chosen this structure)
Documents without these columns have to be upgraded.

<table>
<thead>
<tr>
<th>Element</th>
<th>Author / Reviewer</th>
<th>No of docum. SG4/....</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Quality management system</td>
<td>Author: Andrew / Review: Tim</td>
<td>N301R2</td>
</tr>
<tr>
<td>2</td>
<td>Management responsibility</td>
<td>Author: Robert / Review: Chris</td>
<td>N302R2</td>
</tr>
<tr>
<td>3</td>
<td>Resource management</td>
<td>Author: Tim / Review: Andrew</td>
<td>N303R2</td>
</tr>
<tr>
<td>4</td>
<td>Product realization (design and development)</td>
<td>Author: Chris / Review: Markus + Horst Frankenberger</td>
<td>N304R3</td>
</tr>
<tr>
<td>5</td>
<td>Product realization (production and servicing)</td>
<td>Author: Karen / Review: Robert</td>
<td>N305</td>
</tr>
</tbody>
</table>
Process oriented structure of the document was further decided. This means the following three phases:

6.1 Pre-audit phase
- Quality Management System
- Management Responsibility
- Resource Management
- Product realisation
- Measurement, analysis and improvement

6.2 Audit phase
- Quality Management System
- Management Responsibility
- Resource Management
- Product realisation
- Measurement, analysis and improvement

6.3 Post audit phase
- Quality Management System
- Management Responsibility
- Resource Management
- Product realisation
- Measurement, analysis and improvement

The following points of the agenda have been postponed to the next meeting:

5. Assembly of elements, group discussion
5.1 Gap Analysis QSIT and ISO 13485:200X (Karen + Chris + others)
5.2 Additional regulatory auditing requirements for quality management systems (Input from all regions)

**Document available only from Asia SG4 / N351R1.**

5.3 Sequence of audits elements (Input by Johann) and other useful strategy principles. Johann Rader will change his document from element orientation to process orientation according to ISO 13485:200X.

**Next Meetings:**

10 to 12 February 2003
Rockville, with FDA
(via Christine)

24 to 26 May 2003
Tokyo in conjunction with GHTF Plenary
(via Morichika)

Interim Chairman     Secretary
Horst Frankenberger    Dierk Bellwinkel

Luebeck, 03. 12.2002

Annex:
Regulatory audit strategy