SG4 / N52

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 surveilliance 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.

QS Regulation Chapter 21 CFR Part 820 (QS regulation text)	ISO 13485:200X Chapter (ISO text) Master numbering!	Regulatory audit objectives Objectives, remarks, guidance + regional notes

Tasks from Luebeck for next meeting in Rockville:

	Element	Author / Reviewer	No of docum. SG4/….	Status
1	Quality management system	Author: Andrew / Review: Tim	N301R2	
2	Management responsibility	Author: Robert / Review: Chris	N302R2	
3	Resource management	Author: Tim / Review: Andrew	N303R2	
4	Product realization (design and development)	Author: Chris / Review: Markus + Horst Frankenberger	N304R3	
5	Product realization (production and servicing)	Author: Karen / Review: Robert	N305	

6	Measurement analysis and improvement	Author: David Marshall / Review: Johann	N306R2	

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

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

7. 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
Horst Frankenberger

Secretary
Dierk Bellwinkel

Luebeck, 03. 12.2002

Annex:
Regulatory audit strategy