Global Harmonisation Task Force, GHTF, Study Group 4: Auditing Meeting on 12 – 14 May 2002 in Singapore

Chair: Dr. Markus Zobrist, Swissmedic

Participants:
Mr. Markus Zobrist, Swissmedic, Switzerland, step in chairman
Mr. Dierk Bellwinkel, EUROM VI, Europe, step in secretary
Mr. Tim Missios, Boston Scientific Ltd, Canada
Mr. Kenji Aoyama, JFMDA (TUV Rheinland Japan), Japan
Mr. Morichika Tanemura, JFMDA, Japan, Sakura Finetechnical Co.
Ms. Karen Coleman, ORA, FDA, USA
Ms. Christine Nelson, CDRH, FDA, USA
Mr. Robert L. Turocy, Philips Medical System, USA
Mr. Andrew Muir, TGA, Australia
Ms. Makiko Isozaki, MHLW GMP Section, Japan
Mr. Daisuke Koga, MHLW, Japan
Mr. Chen Zhigang, Centre for Medical Devices, China
Ms. Zhang Mingzhu, Centre for Medical Devices, China
Mr. Albert T.W.Li, Ind. Technology Research Institute, Taiwan
Mr. Johann Rader (TUV Product Service) Germany
Mr. George CH TAN (Igel CM Laboratory Pte Ltd), Singapore

Apologies arrived from, Ingeborg Hagerup-Jenssen (Norway) and David Marshall (CEC/BSI)
The chairman Horst Frankenberger felt seriously ill shortly before this meeting, the group wishes him a quick and healthy recovering.

1. With 7 members from the regulator side and 5 from industry side the group is nearly balanced. Objections were discussed with the chairman and the GHTF Secretary, the result is already published on the web-site.

2. The endorsed documents as well as ethic issues are for revision or discussion at the next meetings.

3. The proposed merger of SG 3 and SG 4 was treated at the last Steering Committee meeting with the result, that SG 4 is to be expected to finalise its documents before the two SG are merged. The merging date might have to be reconsidered by the SC.

4. The work items for this meeting are:
   Supplement No. 4 “Compilation of audit documentation (GHTF SG4(99)24Rev2)” and
   Audit strategy for regulatory auditing of quality systems (GHTF SG4(99)32

5. Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – General Requirements – Supplement 4: Compilation of Audit Documentation

   This document is addressed to auditors only and does not address the exchange of documentation between auditing organizations. This in mind the document was revised and led into the final document SG4(99)24Rev3.

6. Proposal to develop an "Audit Strategy for Regulatory Auditing of Quality Systems" SG4(99)32

   After a report by Mr. Robert Turocy on QSIT (his folios are attached), the existing situation shows:

Country/Region	Published Audit Strategy	QS Requirements
USA	QSIT	21CFR820 (by law)
Canada	QS requirements under development	ISO 13485 obligatory
EU	----------	9001:2000 + EN 46000 or +ISO 13485
China	Only in Chinese available	9001:2000, ISO 13485
Japan	----------	Implementing ISO 13485:200X
Australia	----------	ISO 13485, accepting EN 46000
Taiwan	----------	ISO 13485

   Before deciding the following question has to be cleared;

- Suitability or gaps of QSIT to their national regulations.
- Suitability or gaps of QSIT for ISO 13485:200X
- Suitability or gaps of QSIT for ISO 13485:1996
- Suitability or gaps of QSIT for ISO 9001:2000

Elements of ISO 13485:1996 not explicitly covered in QSIT:

- 4.3 Contract review
- 4.5 document and data control
- 4.6 purchasing
- 4.7 control of customer supplied products
- 4.8 product identification and traceability
- 4.15 handling, storage, packaging, preservation and delivery
- 4.18 training
- 4.19 servicing

After discussion on the advantages and disadvantages of the different possibilities starting the work for an auditing strategy document, the group decided the following:

Scope:

Generate a quality system audit strategy for regulatory purposes and use QSIT as a reference to allow one audit to satisfy the needs of multiple jurisdictions

Incorporate the principles of the document "Part 3: Estimation of Audit Duration" SG4(99)10

Assumptions:

Members of the SG 4 will do the work
ISO 13485:200X will be final within 12 months
ISO 14969 guidance document (revision of ISO 14969:1999) completed within 12 months

Benefits among others:

For the regulatory body:
Improved audits result in improved quality systems and product quality
Achieve greater consistency in audits both within and between regulators
Allowance of greater collaboration between regulators
Increase quality of, confidence in and acceptance of audits by other regulators
Saving resources
Guidance for new emerging countries

For the manufacturers:
Improved audits result in improved quality systems and product quality
Saving resources by reducing the number of audits
Consistency in audits
One approach for auditing
Easier preparation for the audits

Objectives:

- To identify elements on an audit strategy and prepare guidance on these elements
- Gap analysis of QSIT to ISO 13485:200X
- Follow the structure of ISO 13485:200X
- What to and how to
- Stakeholders will provide input in the form of comments to the proposed guidance

Possible elements of the audit strategy document:

1. Quality management system
   Author: Andrew / Review: Tim
2. Management responsibility
   Author: Robert / Review: Chris
3. Resource management
   Author: Tim / Review: Andrew
4. Product realization (design and development)
   Author: Chris / Review: Markus + Horst Frankenberger
5. Product realization (production and servicing)
   Author: Karen / Review: Robert
6. Measurement analysis and improvement
   Author: David Marshall? / Review: Karen

7. Additional regulatory requirements for quality management systems
8. Sequence of audits elements
   Input by Johann
9. Estimation of the audit duration and of the elements

Tasks for the members:

Prepare statements of audit strategy steps 1 through 6 with necessary background information/explanations on how to carry them out

- Johann Rader + Andrew Muir: No. 7 from Europe and Australia side
- Karen Coleman: No. 7 from USA side
- Organiser Morichika Tanemura: No. 7 from Asia
- Anne-Marie Coutu: No. 7 from Canada
- Karen + Chris: Gap analysis QSIT and 13485:200X
  (input from all members)

Timeframe: 6 months for working draft

1st step: End of July proposals to reviewer
2nd step: Draft sent out to Study Group on 23 August

Next meetings

16 / 17 September 2002 in Luebeck
10 / 11 February 2003 in USA

25 – 30 May 2003 GHTF Conference in Tokyo

5.7 SG4(00)5 Document on report on the application of General requirements by regulator agencies is not available. Horst or Markus have to require it from Robert Allen

6. Further Points:

6.1 ISO CD 19011 has to be checked if there is any influence to our documents (will be done by Albert until end of August)

6.2 No expert for IVD is available. All regulators cover also IVD. In Japan IVDs are still under pharmaceutical rule, but possible changes are under discussion. Decision has to be taken after presenting a proposal by SG 1.

Any other business

At the moment the merger of SG 3 and 4 is open. It has to be clarified that in May 2003 this item can only be completed when the work plan is accepted by the Steering Committee.

Singapore, 14 May 2002