SUMMARY REPORT
GHTF – SG4 WASHINGTON, D.C. - MEETING

Location: Ronald Reagan Office Building and International Trade Center
1300 Pennsylvania Avenue
Washington, D.C. 20004 USA

Sunday	September 30, 2007	09.00 to 17.30
Monday	October 1, 2007	08.30 to 17.30
Tuesday	October 2, 2007	08.30 to 14.30

Chair: Markus Zobrist
Secretary Jan Welch

Participants:

Name	Country	Govt	Industry	CAB	Member/ Observer
Members					
Coleman, Karen	USA	X			M
Edelhäuser, Rainer	EU	X			M
Hamelin, Frédéric	CAN	X			M
Kato, Yuichi	JAP	X			M
Koenig, Bertram	EU		X		M
Krumme, Reiner	EU			X	M
Lartigue, Philippe	EU		X		M
Li, Albert	TWN	X			M
Missios, Tim	CAN		X		M
Simondet, Francois	EU		X		M
Snaith, Roger (for Milic)	AUS	X			M
Welch, Jan	USA	X			M
Worroll, John	EU			X	M
Zobrist, Markus	EU	X			M
Koga, Yukiko	JAP				O
Perez, Ana	URAGUAY				O
Guzman, Fernando	PERU				O
Total: 14 Members		**8**	**4**	**2**	**14**
Excused:					
Robert Turocy	USA		X		Retired from M
Shigetaka Muira	JAP		X		M
Dragana Milic	AUS	X			M

Goals of the meeting:

- Discuss the status of SG4 N33 Proposed Document
- Define content and document structure for new work item SG4 N83 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 1 Multi-site Audits and Audits of Suppliers
- Align with SG3 on SG3 N17 Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers
- Give input to new SG3 work item N19, Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies
- Define prerequisites for Software auditing together with SG3
- Participate in Subgroup addressing manufacturer definition
- Set up an action plan and work on new item "Auditing Software"

1. Welcome by the chairman

Markus Zobrist welcomed participants. The apologies as listed were received and the membership list was updated after the roll call. The agenda was adopted with one item added “Clarification of the status of certification issued for standards like ISO 14971” (discussion requested by Rainer Edelhäuser) and on “Interpretation of the competency requirements for auditors listed in N28” (discussion requested by John Worroll.

2. SG4/N33R16:2007 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

SG4 had previously submitted this document to the Steering Committee suggesting to allow for an extra 2 months consultation period in order to receive other opinions on items which could not be resolved by a full consensus within the study group. The Steering Committee decided, however, that this document was urgently needed and adopted it with some modifications.

SG4 is recommending that auditing organizations use this document and give a feedback on the usability allowing SG4 to clarify also previously raised question about possible inconsistencies or whether or not this document might be too prescriptive. These comments are to be held for future consideration.

3. New Work Item – SG4 N83 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 1 Multi-site Audits and Audits of Suppliers

The group decided to split this work into two documents, the first SG4 N83 covering exclusively the multi-site auditing which needs a process including extra steps for the planning and for the wrap up as well as special auditing considerations for the interaction of quality management systems of different sites. The working document was structured and contents were discussed which are to be drafted (as a

homework assigment to 3 teams) until next meeting in Paris. This document will fully support the subsystem approach of SG4 N30.

4. New Work Item – SG4 N84 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 1 Auditing of Supplier Control.

The group reviewed the scope of SG 3's N17 document which gives guidance on supplier control and assigned homework to subgroup preparing contents for this document until next meeting.

Supplier controls might include recommendations for conditions when the auditing organization will have to audit the supplier, keeping in mind that the new definition of the GHTF term "manufacturer" will exclude any form of supplier (e.g. such as sterilizers). The legal basis for conducting regulatory audits at suppliers, however, is not alike in the different jurisdictions.

5. SG3 N19 Document on severity of observations

SG3 and SG4 had been mandated to refine the classification of severity of observations. There are two approaches possible, one looking from the quality management theory and another one from the auditing practice. The chairs of both SGs agreed that SG3 would take the lead but involving members of SG4 in this work giving the input from SG4. This arrangement was also discussed in the Steering Committee which finally dropped previously raised concerns. The goal is to have more specific, refined definitions for terms used when discussing audit results.

6. Define prerequisites for Software auditing together with SG3

Brian Fitzgerald, chair of the Ad Hoc Group on Software explained the background for their recommendations to the Steering Committee to initiate work on guidance in the domain of software. (The chairs of SG3 and SG4 had responded in a written memo to the Steering Committee on this matter and have been raising questions).

It was confirmed, that the Software Ad Hoc Group is making their recommendations based on internationally recognized software standards. In a further discussion questions on terms like "software QMS" were raised, it was explored on how software validation could eventually be seen as part of process validation (SG3) and on how software could be audited as part of quality management system audit (SG4).
An IEC 62304 Medical device software – Software life cycle processes is existing, an international standard for software used in production and quality control is however missing at this point. The quality of device software tends to be reviewed as part of a design dossier evaluation whereas software of critical production and quality control equipment may be subject to a QMS auditing process.

No conclusive items remained left that either one of the study groups could tackle right away. Discussions will continue. Open is as well if some guidance on software could be included in TC 210's ISO14969.

7. Relationship to CASCO

The chairs of the Steering Committee and of SG3 and SG4 are to explore the possibilities for collaboration with CASCO (ISO Technical Committee developing the conformity assessment standards) and to report to the Steering Committee

There was also a brief discussion on the draft ISO 17021-2 which will have an impact on SG4 N28. John Worroll volunteered to closely follow the work of CASCO as a member of BSI, no official liaison status between GHTF and CASCO has been established yet.

8. SG4(PD)/N28R3 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements

N28 was the first document issued by SG4 and was completely revised and restructured taking into account new ISO standards for Auditing and for Conformity assessment. This revision was approved by the Steering Committee as a proposed document for comments due until 15 May 2008:
http://www.ghtf.org/sg4/sg4-proposed.html

9. New Agenda Items

From a discussion about our position with respect to certification against standards ISO 14971 or against sterilization standards it may be concluded, that such certification is of no regulatory or GHTF concern as long as it keeps entirely a status of a voluntary certification with no impact whatsoever on the conformity assessment procedure of medical devices.

There was some discussion about auditor competencies per the criteria in N 28. There was general discussion about the members' experiences with regard to hiring, experience, and training of audit personnel.

10. Recognition of Retiring Study Group Members

The chairman recognized Karen Coleman and Bob Turocy who are retiring and are concluding their service to GHTF. The chairman thanked both members for their contributions over the years. Both members were presented with signed certificates from all the study group members.

11. Next Meeting Plans

The next meeting is April 1-3, 2008 in Paris, France.

12. Updated Work Plan

There was some final discussion on meeting dates and the work plan. The following chart summarizes the study group plans.

Year	2008					2009			
Quarter	IV	I	II	III	IV	I	II	III	IV
N 28 Part 1			Stage 5		Stage 6				
Supplement No. 1 N 83 Multiple Site Audits			Stage 2		Stage 4			Stage 6	
Supplement No. 2 N 84 Supplier Control Audits			Stage 2		Stage 4			Stage 6	
SG4 Meetings			April 1-3 France		? Oct Canada				

13. New Agenda Item

There was some discussion on John's item about auditor competencies per the criteria in N 28. There was general discussion about the members' experiences with regard to hiring, experience, and training of audit personnel.

14. Action Items from Meeting

No	Action point / Task	Responsible	Contact	Due date	Results
1	N83 and N84 working groups to provide draft sections to the secretary	SG 4 members	SG 4 Secretary	Feb 15, 2008	
2	Secretary to send out collated N83 and N84 to study group	SG 4 Secretary	SG 4 Secretary	March 1, 2008	

Berne, January 24, 2008

Markus Zobrist, Chair GHTF SG4