Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG4 N93

GHTF

MINUTES
GHTF – SG4 Toronto, CANADA MEETING

Location: Westin Harbour Castle
1 Harbour Square
Toronto, ON M5J 1A6 Canada

Sunday	May 10, 2009	09.00 to 17.00
Monday	May 11, 2009	08.30 to 17.00
Tuesday	May 12, 2009	08.30 to 15.00

Chair: Jan Welch Secretary: Elisabeth George

Participants:

Name	**Country**	**Govt**	**Industry**	**CAB**	**Member/ Observer**
Members					
Edelhäuser, Rainer	EU	X			M
George, Elisabeth	USA		X		M
Tsai, Armand (alternate)	CAN	X			M
Koenig, Bertram	EU		X		M
Lartigue, Philippe	EU		X		M
Li, Albert	TWN	X			M
Missios, Tim	CAN		X		M
Preiss, Stefan	EU			X	M
Ruff, Robert	USA	X			M
Snaith, Roger(alternate)	AUST	X			M
Studer, Peter	EU	X			M
Worrell, John	EU			X	M
Welch, Jan	USA	X			M
Total: 13 Members		7	4	2	13
Observers					

Goals of the meeting:

- *Discussion and finalization of* **PD N83 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 4: Multiple Site Auditing**
- *Discussion and finalization of* ***PD N84 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 5: Audits of supplier controls***
- *Software AHWP Memorandum*
- *Update Study Group 4 Work Plan for 2009-2010*

1. Welcome by Chairperson Jan Welch

Jan Welch welcomed all participants. Ms. Welch described the SC discussions regarding SG's moving to a maintenance mode and specifically discussed SG4's plan post N83 and N84. She described the potential of a subset group working to align with SG3. She informed group that SG3 /N17/2008 Quality Management System – Medical Devices – Guidance on the Control of Products and Service Obtained from Suppliers had been posted as a final document on February 5, 2009. General discussion followed regarding posting of documents and associated communication.

Apologies
Dragana Milic, Francois Simondet, Frederic Hamelin, Shigetaka Miura, Yuichi Miyamoto and Akiko Hayashi did not attend the meeting. Roger Snaith attended as an alternate for Dragana Milic and Armand Tsai attended as an alternate for Frederic Hamelin.

Roll call of the participants
All participants introduced themselves, and the member list was updated. The sign-in list is enclosed as Annex 1 and the revised member list is enclosed as Annex 2. The GHTF web site will be updated with current study group membership information after the meeting.

Adoption of the agenda
The agenda was discussed. The focus of the meeting would be primarily to complete the review of SG4 N83 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing. A review was held of the AHWP Memo dated October 3, 2008 from Brian Fitzgerald. Proposal was made and submitted back to Brian. Discussed objective to finish N83 for presentation to SC for approval in July call and next steps for N84.

2. Report from AdvaMed Ad Hoc Audit Group

Elisabeth George gave informal overview of the AdvaMed Ad Hoc Audit Group. Purpose of the group was to on defining working method for harmonizing on

report format for audit to support industry in reduction in number of audits and ability to leverage reports. Promotion of GHTF SG4/N33.

3. Action items from the previous meetings and telecoms:

The action items from the Paris meeting minutes were reviewed.

Many action items pertained to the N83 document. Most items were completed. Some homework assignments were not completed and submitted. The comment period for N83, once it is ready as a proposed document, was discussed. The plan is to submit the PD in July to the GHTF Secretariat for the SC to consider at its next conference call.

No feedback had been received on the AHWP Memorandum therefore, review accomplished during meeting.

All action items pertaining to N84 the Supplement on auditing of supplier control were completed.

4. Work on the document: N83 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing

Significant time was spent reviewing the previously proposed changes and in confirming clarity of phrases, definitions and flow diagrams. Homework included organizing and formatting.

5. Continuation of Work on the document: N84 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing

Day two of the meeting began at 08:30 May 11, 2009. The meeting began with a review of agenda to ensure objectives for the day were clear and to ensure proper focus to complete N83 and next steps for N84. N83 was completed with only editorial clean up needed by the Secretary. Objective to have updates completed and set to chair by early June for submission to SC. Proposal was for standard review timeframe.

6. An overview of training Methodologies (AHWP)

Discussion regarding optimal methods and techniques for training. Pros and cons were shared regarding use of 3rd Party Companies, Live Training Programs, CBT, Webinars. Future training and use of members to SG was discussed.

7. Review on October 2008 Software AHWP memorandum from Brian Fitzgerald

As no feedback received prior to the meeting, the study group decided to review the proposals submitted by the AHWP, It was determined that some proposals were not necessary however, after discussion the group decided to add applicable references to N30 in Appendix 5. This was agreed upon based on the fact that SW is difficult to audit therefore, there should be a reference to specific attributes to address. Ms. Welch to submit proposal to AHWP with proposal for a 2 month comment period only.

8. Work on the document: N84 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 5 Audits for Supplier Controls.

Day three of the meeting began at 08:30 May 12, 2009. The meeting began with a review of day so that the open issues regarding N84 would be addressed and a detailed plan defined. John Worrell put together review slides to make the open items discussions easier to address. Detailed discussions were held regarding definitions and actions. Discussion included differences in definition of supplier, critical supplier, virtual manufacturer. John Worrell collected the insights and comments. There were also discussions regarding the use of flow charts from N17 and N30.

9. Future SG 4 Meeting Options

Telecom meeting agreed to for final review of N84. John Worrell and Elisabeth George to address logistics. Jan Welch to determine next steps for meetings based on inputs from the SC and SG4.

10. Work Plan and Next Meeting Plans

The following chart summarizes the study group work.

Year	**2009**	**2009**	**2009**	**2010**	**2010**
Quarter	2	3	4	1	2
N28 Part 1					
N83 Auditing of Multiple Site Facilities		Stage 6			
N84 Auditing of Supplier Controls	Stage 2	Stage 4	Stage 6		
N30 SW AHWP Inclusion		Stage 6			
SG 4 Meetings	May 10-15 Toronto	Telecom – N84			To review comments

The following due dates were established:

June: Final N83 submitted to chair
June: SW AHWP N30 Draft to chair for mail to AHWP
July: N83 SC Conference Call
November: N84 SC Conference Call
Q2 2010 : Review and finalize on comments N83 & N84 and determine Maintenance Mode Plan based on Steering Committee Guidance.

11. Action Items from Meeting

No	Action point / Task	Responsible	Due date
1	Complete editorials N83 and send to Chair	Secretary	June 1, 2009. **Completed July 1, 2009**
2	Submit N83 to SC	Chair	1 week post secretary submit. **Completed.**
2	N30 Draft with proposal for AHWP	Secretary	May 11, 2009 **Completed May 11, 2009**
3	Memorandum to SW AHWP	Chair	July 1, 2009 **Completed June 12, 2009**
4	N84 Open Questions to John Worrell	All	Questions reviewed @ meeting. Follow up Memo sent June 1, 2009. **Completed June 18, 2009.** Responses due July 10, 2009
5	Webinar Schedule to finalize N84	John Worrell & Secretary	Scheduled August 27, 2009
6	Future Meetings	Chair	TBD

The meeting was adjourned around 1500.

Toronto, Canada May 12, 2009

Elisabeth George
Secretary, GHTF SG 4

Annex 1 2009 Ottawa meeting sign-in list
Annex 2 Current SG4 member list