

GHTF SG 3
Meeting Minutes
May 7th to 11th, 2007
Los Angeles, USA

Location: FDA Los Angeles District Office
19701 Fairchild
Irvine, California 92612
USA

The following meeting agenda was accepted with the amendment that the optional meeting day of Friday May 11 would not be required.

Monday May 7, 2007

SG3 Meeting

8:45 – 12: 00

All SG3 members

- Opening of meeting
- Administrative issues
- Continue work on guidance documents

Joint SG3-SG4 meeting

13:00 – 17:30

All SG3 & SG4 members

- Discuss common issues related to multi-site auditing and supplier audits

Tuesday May 8, 2007

SG3 Meeting

8:30 – 17:30

(members not participating in SC or SG1-SG3 sub-group on definition of manufacturer)

- Continue work on guidance documents

Joint SG1-SG3 sub-group

8:30-17:30

(Asai, Cobbold, Frey, Trautman, Masaaki)

- Sub-group of SG 1,3 & 4 members to develop GHTF definition of device manufacturer
- Meeting chaired by Mr Alan Kent (SG1)

Steering Committee meeting

13:00 -17:30

(Cobbold, Schoenbuehler)

- SG3 work plans presented

Wednesday May 9, 2007

SG3 meeting

8:30 – 17:30

All SG3 members

- Continue work on guidance documents

Thursday May 10, 2007

SG3 meeting

8:30 – 17:30

All SG3 members

- Official last day of meeting
- Continue work on guidance documents
- Homework assignments
- Formally close meeting

Friday May 11, 2007

8:30 – 17:30

- Additional day available for members to meet

1) WELCOME AND INTRODUCTION

E Cobbold, Chair SG3, opened the meeting at 8:30 am with logistical comments then introduced the new SG3 members : Mr Jan Noupbaev (Medtronic of Canada Ltd., MEDEC) and Mr Dirk Wetzels (BfArM – Bundesamt für Arzneimittel und Medizinprodukte).

Mr. Keith Smith (TGA) and Mr. Dirk Wetzels (BfArM) were unable to attend this meeting.

Attendance Matrix:

Name	Country/Region	Govt	Industry	Observer	Association	Participated	Def of Mfg Sub group
Asai, Hideki	Japan		X		JFMDA	Y	Y
Cobbold, Egan	CAN	X			HC	Y	Y
Dorman-Smith, Victor	EU		X		EUCOMED	Y	
Frey, Gunter	USA		X		NEMA	Y	Y
Kopesky, Ken	USA		X		AdvaMed	Y	
Nakamura, Munehiro	Japan		X		JFMDA	Y	
Nicol, Ken	AUS		X		MIAA	Y	
Noupbaev, Jan	CAN		X		MEDEC	Y	
Schoenbuehler, Werner	EU		X		COCIR	Y	
Smith, Keith	AUS	X			TGA	NO	
Trautman, Kim	USA	X			FDA	Y	Y
Yamamoto, Junji	Japan	X			PMDA	Y	
Yuichi, Miyamoto	Japan	X		X	PMDA	Y	
Masaaki Tsukano	Japan	X			MHLW	Y	Y
Wetzels, Dirk	EU	X			BfArM	NO	

2) GUIDANCE DOCUMENT SG3N17 (CONTROL SUPPLIERS)

The following is a summary of the group discussions or activities that occurred during the editing of document SG3N17 over the 4 days the group met:

- Title of the document was changed to more accurately reflect the regulations and standards used by the GHTF members. This same change was made throughout the body of the document. The new title is *Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers*.
- Significant discussion arose around the attempts to differentiate between external suppliers and internal suppliers.
- Significant modifications were made to the process flowchart
- While G Frey, E Cobbold, K Trautman, H Asai and M Tsukano participated in the “Definition of Manufacturer” *ad hoc* group, V Dorman-Smith chaired the remainder of the group in the editing and further development of SG3 N17. J Noupbaev served as secretary for the group.
- The output of the meeting was called N17R5 LA Working Version Day 4

In preparation for the October 2007 meeting of SG3, the following work items were assigned to members for **completion and submission to the Chair and Secretary by July 31, 2007**

Responsible Party	Issue
Jan Noupbaev	Review text in section 3.5 and compare with 3.5 in flowchart
Victor Dormann-Smith	Review text in section 3.7 and compare with 3.7 in flowchart
Kim Trautman	Review and edit examples
Egan Cobbold	Review text in section 3.3 and compare with 3.3 in flowchart
Hideki Asai & Munehiro Nakamura	Review text in section 3.4 and compare with 3.4 in flowchart
Ken Kopesky	- Review text in section 3.6 and compare with 3.6 in flowchart - Review and edit examples

3) SG3 MEMBERSHIP LIST

The GHTF website membership list and contact information will be updated based on comments and corrections received at LA meeting.

Responsible Party	Issue
Gunter Frey	Submit revised and corrected membership list to GHTF webmaster for posting on GHTF SG3 website

4) JOINT SG3-SG4 MEETING (DISCUSS SUPPLIER AUDIT)

Joint meeting SG3/4:

Markus Zobrist, Chair SG4, opened the joint meeting between SG3 and SG4.

This joint session was suggested by the chairs of the respective study groups, in order to address auditing of suppliers and subcontractors.

The Chair of SG3 presented the introduction and scope of N17 (control of suppliers). Emphasis was placed on the fact that there are limited requirements in ISO13485:2003 related to the control of outsourced processes and does not provide a definition of what is considered to be effective control or what methods of controls a manufacturer should consider (see ISO 13485:2003, Sections 4.1 and 7.4 , Articles 5 and 37 through 39 of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and *in vitro* Diagnostics (MHLW Ministerial Ordinance No. 169, 2004.)

Markus Zobrist suggested that the output of this document could be used as an input into the future SG4 document regarding auditing of suppliers; however, he qualified it as limited input, as SG4 feels it important to also make provisions to the process of auditing suppliers.

Questions regarding terminology as well as specificity of the guidance document (e.g. outsourcing design activities, outsourcing manufacturing processes, etc.) were raised and discussed by in general terms.

Other questions that were raised included:

- Is outsourcing of, for example design activities, a special case that needs to be addressed separately? If a manufacturer outsourced design, does the manufacturer have the necessary expertise in house to verify/validate that design? It was suggested that there should be at least a degree of assurance that the manufacturer reviewed and assured that the validation was performed according to the manufacturer’s specifications.
- How to audit Manufacturers of a finished medical device that is also a supplier of a similar device to another legal entity (manufacturer) that also places the device on the market.
- How to address the scenario of multiple suppliers of the same product (non-single source).
- Products or services coming from within the same quality management system (process oversight) vs. coming from entities with different quality management systems (product oversight).

SG3 agreed to provide the draft version developed in LA to SG4 and they agreed to provide feedback on the document.

Responsible Party	Issue
Chair SG3	Provide copy of draft N17 document to SG4 for comment.

5) 11th GHTF CONFERENCE - WASHIGTON DC, OCTOBER 3-4, 2007

Egan Cobbold presented to the group the schedule for the 11th GHTF conference (SG meetings will begin Sunday, September 30th and wrap up the afternoon of Tuesday October 2rd. The conference will begin October 3rd , end on October 4th).

The Chair of SG3 encouraged all members to participate in the GHTF conference as well as the Joint GHTF SG3 / TC 210-WG1 meeting on October 5th at the AdvaMed offices.

The attached file represents the current plan for the 11th GHTF Conference, Washington October 3-4, 2007. A final version will eventually be posted to the GHTF website.

E Cobbold volunteered to participate as a speaker in the conference workshop on “Quality Systems Auditing for Multi-purpose Inspections : Experience and Practical Advice-Giving” and to be a trainer at the PAHO/Latin America training session scheduled for Saturday October 6th, 2007.

<i>ACTION ITEM</i>		
Responsible Party	Issue	Closure
E Cobbold	Get from Gail Costello details of conference workshops and training program and provide to SG3 members for consideration as participation as speakers/presenters.	

6) JOINT SG3 - TC 210 / WG1 MEETING FRIDAY OCTOBER 5, 2007

The Chair of ISO TC 210/WG1 and the members of SG3 have agreed to hold a joint meeting in Washington, DC, to discuss the future plans for ISO 13485 and ISO/TR 14969. The discussion will be driven by the results of the global user Questionnaire that is scheduled for completion June, 2007

The joint meeting is to be held Friday October 5th, 2007, 9am to 1 pm , at Advamed’s office, 701 Pennsylvania Ave., Suite 800, Washington, DC.

7) NEXT SG3 MEETING DATES AND LOCATION (2008 -2009)

Canada will assume Chairmanship of GHTF in 2008.

January/February 2008: Possible location Australia – Ken Nicol to investigate the possibility of a meeting in Sydney or Canberra.

Early June 2008: Possibly Southern France (PDI) – Gunter Frey to investigate the possibility of hosting a meeting at a GE facility in Southern France (or elsewhere in Southern Europe)

Fall/Winter 2008: Location to be determined

Spring 2009: Canada (Possibly Toronto as part of 12th GHTF conference to be hosted by Canada)

8) WORK PLAN PRESENTED TO SC

E Cobbold presented to the SC the proposed SG3 work plan for 2006 to 2011. The plan was accepted as presented.

N17 Supplier Control (Priority 1):

- Stage 2: to be completed in 4th quarter 2007
- Stage 3: completed in end of 2007
- Stage 4-7: completed by July 2008

N18 CAPA (Priority 2):

- Stage 2: start draft in text in 1st quarter 2008 - end work by January 2009
- Stage 3: completed by March 2009
- Stage 4-7: completed by early 2010

N19 QMS Deficiencies (Priority 1):

- Revised NWIP submitted to SC for approval: May 2007
- Stage 2 - 7 : start drafting text of guidance in 4th quarter 2007 - end work by 1st quarter 2010

At the November 2006 Brussels meeting of the SC, SG3 withdrew New Work Item Proposal (NWIP) N19 for consideration because the SG felt that more discussion within the group was needed to better clarify the objectives of the work item. The original NWIP for N19 was reviewed by the SG3 members during the LA meeting and significantly amended to more accurately reflect what the SG felt the objectives of the work item should be. Version R1 will be re-submitted to the SC for approval prior to the SC's June 2007 teleconference..

The group felt that in order to achieve recognition of audits across multiple jurisdictions, it is necessary to keep regulatory requirements harmonized; to define harmonized auditing approaches (acceptable to all regulators); and to harmonize the interpretation of audit results. Harmonization of interpretation of audit results is intended to result in a common output and understanding and not to "harmonize" on actions resulting from such audits as these country/region specific actions would be driven by the legislative options available to the various geographic regions.

The group also thought that a pilot exchange program, similar to SG2's NCAR, could be considered as a model for the exchange of audit report information and common understanding of the significance of audit/inspection findings.

SG1/SG3 Joint work item on Definition of Manufacturer (Priority 1):

- First meeting of ad hoc group held May 2007
- Completion of SG3 involvement in ad hoc work by October 2007

SG3/SG4: Joint work item on Auditing of Suppliers:

- First joint meeting with SG4 held May 7, 2007 to discuss work item. Additional meetings to be held as required.

Revision of ISO13485 jointly with ISO TC210 / WG1:

- Significant changes to ISO13485 are foreseen as a result of the 2012 revision of ISO 9001. Therefore it is anticipated that greater involvement of GHTF SG3 and ISO TC 120/WG1 with ISO TC 176 will be required in order to be fully engaged in the 9001 revision process. During the open group discussion on this work item a proposal was made to more rigorously separate

ISO13485 from the quality management systems standards written by ISO TC 176 in order to minimize the impact of changes of 9001 on ISO 13485.

Summary of GHTF Steering Committee meeting:

W. Schoenbuehler presented to the group a summary of the key topics that were discussed by the SC at their meeting of May 7-8, 2007:

- Electronic submissions (HL7 format)
- New guidance on 510(k) submissions will be available soon
- The *ad hoc* software group will not become a Sub Group or join SG3. Rather it will remain as an *ad hoc* group and report to the SC. The group may be tasked with ensuring that software issues are considered by the five Study Groups within their SG documents. The *ad hoc* group provided a draft report to the steering committee. The proposal for the *ad hoc* group to join SG3 as a subgroup was rejected by the steering committee.
- SG3, (software controlled processes - Recommendation #8) to reference software controlled processes in SG3/N99-10 and the software exception currently in place, to make clear that process validations applies to software design activities, as it is critical for proper manufacturing process validation, where software controlled processes are present. Further, the proposed text of the new European MDD now contemplates software validation, software verification, and software lifecycle activities.
- Liaison to be developed with CASCO (Conformity Assessment Committee creates high level horizontal standards like ISO 17011 and ISO 17021 to replace former ISO guides 61 and 62).
- The efforts around UDI (Unique Device Identifier physically on every single device, including disposables and single use devices, implants, etc.) are still on-going; however, there are numerous concerns and challenges foreseen, such as: is it merely being forward looking for new devices? How to address field upgrades, etc. This initiative was started with the intent that it facilitates device reporting by users. L Kessler (FDA) continues to be optimistic that this is achievable.
- Guidance on the control of “outsourced” processes should also include software as 25% of adverse events currently can be traced back to software.

E Cobbold presented to the group a summary of his presentation to the SC:

- The proposed SG3 2006 to 2011 work plan was presented to the SC and accepted as is. Some members of the SC were concerned that SG3 had proposed a modification to the priority of work items N18 and N19 without prior consultation with the Steering Committee.
- Some members of the SC continue to lobby for an amendment of ISO 13485:2003 to include ISO 14971 based risk management activities. In 2006 SG3 submitted to ISO TC 210/WG1 its position on this topic which is that ISO 13485:2003 should not be amended to include ISO 14971 activities as existing GHTF and ISO guidance already exists on how to integrate ISO 14971 risk management activities into an ISO 13485:2003 quality management system. It was pointed out that ISO13485:2003 is not a GHTF document and the desire to amend ISO 13485:2003 should be brought to the attention of the Chair of TC210/WG1.
- The SC is planning to hold a joint meeting with AHWP in Kuala Lumpur March 3-7th, 2008.
- The SC has asked all SGs to identify obstacles for implementation of guidance documents developed by GHTF.
- The SC is requesting that SGs use best practices during meetings and between face to face meetings. (e.g. videoconferences, teleconferences, “homework”, etc.) It was pointed out to the SC that SGs do not work on a single document and further and participates in other groups’ activities (e.g. joint SG3-TC210/WG1 meetings)

- Janet Trunzo reminded and urged members wishing to participate in the 11th GHTF Conference in Washington to make their reservations as soon as possible (see AdvaMed website for further hotel recommendations and details, http://www.advamed.org/publicdocs/ghtf_oct_2007.html).

<i>ACTION ITEM</i>		
Responsible Party	Issue	Closure
All Members	Prepare for development of N19 Guidance document	
E Cobbold	Submit revised NWIP for N19 to SC for there review and approval in advance of the next SC teleconference	

9) OTHER

Mr Larry Kessler, Chair GHTF, briefly joined the group in the morning of May 9th as an observer. He also posed to the group the question: what should be done to facilitate mutual acceptance of inspection/audit results by the various regulatory authorities globally. The group suggested that in trying to keep step with where ISO 13485:2003 is expected to go in the future, the medical device sector may be best advised to develop a formal relationship with TC176 (similar to SG3's association with TC210) to increase appropriate regulatory presence at that level in the development of ISO9001, etc.

Also observing on the afternoon of May 9th were Mr Tim Ulatowski, US FDA SC member, and Mr Roland Rotter, Health Canada SC member.

**** Submitted May 28, 2007 ****