GHTF SG 3
DRAFT Meeting Minutes
September 30 – October 2, 2007
Washington DC, USA

Location
Washington, DC
Ronald Reagan Building and International Trade Center,
1300 Pennsylvania Ave, NW
Washington, DC 20004

Objective of meeting
i) advance the drafting of SG3 guidance document N17; ii) SG3 representatives participate in joint meeting with SG1, Steering Committee, and software ad hoc group; iii) agree on plan of action to complete document N17 by end of 2007 and to commence work on new SG3 documents N18 and N19.

Meeting Agenda

Sunday September 30, 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 – 17:00)
All SG3 & SG4 members

- Discus common issues related to multi-site auditing and supplier audits
- Discuss Joint SG3-SG4 memo to steering committee re: clarification of work items related to software ad hoc group

Monday October 1, 2007
SG3 Meeting (9:00 – 17:00)
(members not participating in SC or SG1-SG3 sub-group on definition of manufacturer)

- Continue work on guidance document N17

Steering Committee meeting (9:00 -11:00)
(Cobbold)

- Report to SC on SG3 work plans and status of work items

Joint SG1-SG3 sub-group (13:00-17:00)
(Asai, Frey,Trautman,)

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

Tuesday October 2, 2007
SG3 meeting (9:00 – 17:00)
All SG3 members

- Continue work on guidance document N17
- Develop plan to commence work on N18 and N19

1) WELCOME AND INTRODUCTION

E Cobbold, Chair SG3, opened the meeting at 9:00 am with logistical comments, followed by review and acceptance of agenda. Members and observes in attendance were:

Name	Country/ Region	Govt	Industry	Observer	Association	Attend SG3	Def of Mfg Sub group
Arglebe, Carlos	EU		X		COCIR	**Y**	
Asai, Hideki	Japan		X		JFMDA	**Y**	**Y**
Chan, Tony	US			X	Tech Expert	**Y**	
Cobbold, Egan	CAN	X			HC	**Y**	
Dorman-Smith, Victor	EU		X		EUCOMED	**Y**	
Frey, Gunter	USA		X		NEMA	**Y**	**Y**
Jan Noupbaev	CAN		X		MEDEC	**Y**	
Kopesky, Ken	USA		X		AdvaMed	**Y**	
Miyamoto, Yuichi	Japan	X			PMDA	**Y**	
Nakamura, Munehiro	Japan		X		JFMDA	**Y**	
Nicol, Ken	AUS		X		MIAA	**Y**	
Smith, Keith	AUS	X			TGA	**Y**	
Takae, Shinichi	Japan	X			MHLW	**Y**	
Trautman, Kim	USA	X			FDA	**Y**	**Y**
Wetzels, Dirk	EU	X			BfArM	**Y**	
Infante, Gabriela	Costa Rica			X	PAHO	**Y**	
Maidana, Anibal	Paraguay			X	PAHO	**Y**	
Escobar, Orles	Honduras			X	PAHO	**Y**	
Total = 18		6	8	4		**18**	**3**

2) REVIEW OF MINUTES FROM LAST MEETING

K Trautman proposed the acceptance of the draft May 7-11, 2007, Los Angeles meeting minutes as final. The proposal was seconded by G Frey and supported by all members. A summary of the final minutes will be posted on the GHTF website.

3) GUIDANCE DOCUMENT SG3N17 (CONTROL SUPPLIERS)

Some progress was made over the 3 days on the development of document N17. However, because of the unavoidable need for several members of SG3 to take part in joint meetings with other Study Groups, ad hoc groups and the Steering Committee, during the course of SG3's regularly scheduled meeting times, actual progress fell short of what was anticipated. Therefore the planned goal of having a draft version of N17 ready for public distribution and comment by the end of 2007 is now not possible. Moreover, considering the amount of work that is still required, the earliest

a public draft could be made available would be after the next meeting of SG3 which is scheduled for the first week of February 2008.

The progress that was achieved focused primarily on refining definitions and processes, and providing good guidance and examples of objective evidence.

At the end of the third day several volunteers agreed to develop additional text related to the following sections of the working draft version (Washington Day 3) of SG3 N17. The output of these work items will be discussed at the February 2008 meeting of SG3

Work item 1
Volunteer: Ken Nicol
Section: 3.3 Supplier evaluation and acceptance.
Task: Provide wording on Validation. Consider also validation of non-verifiable processes at supplier's location

Work item 2
Volunteer: Munehiro Nakamura and Hideki Asai,
Section 3.3.1
Task: Text needs to be checked for redundancy and overlap. Text on "serviceing" and "QA" needs to be added.
Section 3.3.2
Task: Needs text to introduce section.

Work item 3
Volunteer: Jan Noupbaev
Section 3.3.4 Demonstration and evaluation of supplier's ability
Task: Following the qualification process and resulting acceptance of a supplier the applicable agreements (e.g. purchase agreement, quality assurance agreement) have to be reviewed and amended

Work item 4
Volunteer: Munehiro Nakamura
Section 3.4 Finalization of controls and responsibilities
Task: Mune's homework that was originally prepared for the Washington meeting is currently more product oriented and should be expanded to include service)

Work item 5
Volunteer: volunteer required
Section: 3.5.4 Analyse data
Task: Text to be developed to describe purpose of data analysis and method .

Work item 6
Volunteer: Kim Trautman
Section: Appendix A: Examples of Outsourcing. Example 5 : Purchasing of a medical device from a supplier to be distributed under the name or mark of the manufacturer
Task: This example will need to include the controls identified for Example 1 and 2 plus some additional aspects

Last version of working draft saved as "SG3(WD)N17R5 Washington Working Version Day 3.doc" (Note, some SG3 members may have an electronic version of N17R5 that refers to Day 4 in the file name. This version may have been unofficially circulated following the Washington meeting. The Day 3 version that accompanied these minutes is identical to the Day 4 version and should be considered the official version of the work performed in Washington.)

4A) JOINT SG3-SG4 MEETING

Members of both study groups gave there unanimous support to the joint SG3-SG4 memo that was prepared by the groups. The intent of the memo was to request clarification from the SC and the software ad hoc group on the scope of work that the SC had intended SG 3 and 4 perform in relation to the ad hoc group's recommendations on software verification and audit of the verification of software.

Members also agreed to provide comments on SG4's guidance documents on auditing of manufacturers that use suppliers and manufacturers composed of multiple sites.

Members of SG4 that are able to travel to Germany in February 2008 are invited to participate in SG3's next meeting scheduled for February 2008 in Bonn. The objective of the SG4 member's participation is to assist SG3 in the completion of N17 and to use this information as input to SG4's next work item on the auditing of manufacturers that use suppliers. M Zobrist, Chair of SG4, agreed to attend the meeting and other European based members said that they will also attend.

4B) SPECIAL MEETING WITH SOFTWARE AD HOC GROUP

E Cobbold, K Smith and M Zorbrit (Chair SG4) met for approximately 2 hours with the members of the software ad hoc group to discuss SG3 and SG4s concerns that the scope of work assigned to SGs 3 and 4 was not clear. It is SG3 and 4's opinion that the ad hoc group had combined all types of software into the scope of the work. The SG3 and 4 representatives expressed their concern that the process and purpose of the review and assessment of software that is part of a device's manufacturing process is different from the process and purpose of the review and assessment of software that is a medical device or that is an integral part of a medical device. The SG3 and 4 representatives felt that many of the recommendations made by the software ad hoc as they relate to software that is a device or is part of a device would be best handled by existing expert committees on the subject that are maintained by ISO, IEC etc. The outcome of the meeting with the ad hoc group was that SG3 will do the following:

1) Where appropriate, include references to software in SG3 guidance documents
2) Nominate a representative to act as a liaison member with the ad hoc group
3) Invite a member of the ad hoc group to attend SG3 meetings as an observer.

The software ad hoc group agreed to revise their recommendations for SG3 and 4 that related to SG3 drafting criteria for the verification and validation of all kinds of software, and the regulatory auditing of the verification and validation of all kinds of software by auditors and inspectors.

Responsible Party	Issue
SG3 Chair	Seek 1 volunteer from SG3 to act as liaison with the software ad hoc group.
Ad hoc group Chair	Revise recommendations related to work the SG3 and SG4 had been requested to perform. Re-submit these recommendations to the SC for their consideration and acceptance.

5) REPORT TO SC ON SG3 WORK PLANS AND MEMBERSHIP

E Cobbold presented the SG3 2006-2011 work plan to the SC. The plan was accepted as presented. E Cobbold reported on the recent changes to SG3's membership and that since the arrival of a European regulatory representative the overall balance of regulatory and industry participants from all founding members have now been re-established.

6) PLAN OF ACTION TO COMMENCE WORK ON NEW SG3 DOCUMENTS N18 AND N19.

Two working groups based on regulatory or industry representation were created to start working on the development of N18 and N19. The Industry members group was assigned to start working on N18 (CAPA) and the regulatory members group was assigned to start work on N19 (QMS deficiencies). As there was not enough time available during the Washington meeting to formalize work plans and objectives, work on these new documents will commence in earnest at the February 2008 meeting.

7) NEXT SG3 MEETING DATES AND LOCATION (2008)

Meeting Schedule

Date	**Host & Location**	**Purpose**
February 4, 2008	BfArm, Bonn, Germany	Planning session (Chairs and V-Chairs of SG1+3)
February 5, 2008	BfArm, Bonn, Germany	definition of manufacturer ad hoc group meeting
February 6-8, 2008	BfArm, Bonn, Germany	SG3 working meeting (some SG4 observers)

Because of the joint SG3 – SG4 work items recently assigned to these (i.e. auditing of software, supplier control, and significance of nonconformities) members of SG4 that are able to travel to Bonn have been invited to participate in SG3's meeting in.

March 4-7, 2008	AHWP, Kuala Lumpur, Malaysia	GHTF SC meeting & AHWP training
** June 2008	TGA, Canberra, Australia	(3-5 days), SG3 working meeting

(**note: start date and meeting length to be confirmed)

**** Submitted December 19, 2007 ****