GHTF SG 3
Meeting Minutes
February 6 - 8, 2008
Bonn, Germany

Location

Federal Institute for Drugs and Medical Devices (BfArM)
Room A1.E2.05
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn, Germany

Objective of meeting

1. With the participation of members from SG3 and SG4, complete development of draft guidance document SG3N17: Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers.
2. With the participation of members from SG3 and SG4, and through the use of the "industry" and "regulatory" work groups created at the Washington 2007 meeting, start work on SG3 guidance documents SG3N18 CAPA and SG3N19 QS Deficiencies

Meeting Agenda

	Topic	Representative
1	Welcome and Introduction (apologies/time/safety/lunch/admin support/other)	E Cobbold D Wetzel
2	Acceptance of agenda	All
3	Review of minutes from last meeting	All
4	Guidance Document SG3(WD)N17 R5 *Guidance on the control of procured product and suppliers* A. Review homework assignments B. Complete drafting of guidance document C. Assign work items for next meeting	All
5	A. Review status of working groups formed at Washington 2007 meeting B. Commence work on N18: CAPA (Priority 2) and N19 : QMS Deficiencies (Priority 1)	
6	Review 5 yr work plan	All
7	Future meetings A. SG3 Training : Kuala Lumpur, Malaysia March 5-7, 2008 B. SG3 meeting: Canberra, May/June 2008? • Proposed dates in June /08 - do they work? • Other location in May - is this an option? • C. SG3 teleconference between Bonn '08 and Canberra '08. (date and time to be determined) D. GHTF training in Mexico 8-10 October/08 Volunteers for trainers?	A. G Frey, & H Asai B. All C. All D. All

	Topic	Representative
8	Other Business A. Response to Miura-san's proposal to revise ISO13485 (formal statement to SC with SG3's position) B. Review of SC definition document	Members of SG3 (Invite Muira and Warlroth)
9	Closing remarks A. Date and location of next meeting	Chair

1) WELCOME AND INTRODUCTION

E Cobbold, Chair SG3, opened the meeting at 9:15 am with logistical comments and welcomed members and observers. In attendance were:

Name	Country/ Region	Govt	Industry	Observer	Association	Attend SG3	Joint SG Meetings
Arglebe, Carlos	EU		X		COCIR	**Y**	**Y**
Asai, Hideki	Japan		X		JFMDA	**Y**	**Y**
Cobbold, Egan	CAN	X			HC	**Y**	**Y**
Dorman-Smith, Victor	EU		X		EUCOMED	**Y**	**Y**
Frey, Gunter	USA		X		NEMA	**Y**	**Y**
Jan Noupbaev	CAN		X		MEDEC	**N**	**N**
Kopesky, Ken	USA		X		AdvaMed	**N**	**N**
Miyamoto, Yuichi	Japan	X			PMDA	**N**	**N**
Nakamura, Munehiro	Japan		X		JFMDA	**Y**	**Y**
Nicol, Ken	AUS		X		MIAA	**N**	**N**
Smith, Keith	AUS	X			TGA	**N**	**N**
Takae, Shinichi	Japan	X			MHLW	**N**	**N**
**Tobiishi, Shintaro	Japan	X			MHLW	**Y**	**Y**
Trautman, Kim	USA	X			FDA	**Y**	**Y**
Wetzel, Dirk	EU	X			BfArM	**Y**	**Y**
Observers							
Wallroth, Carl	EU		X	X	EUROM 6		**Y**
Edelhäuser, Rainer	EU	X		X	ZLG		**Y**
Total = 14		8	9	2		**9**	**11**

AdvaMed = Advanced Medical Technology Association (USA)
BfArM = Federal Institute for Drugs and Medical Devices
COCIR = European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
EUCOMED = European Association of Medical Device Manufacturers
EUROM 6 = European Industrial Federation – Medical Technology
HC = Health Canada
JFMDA = Japan Federation of Medical Devices Associations
MEDEC = Canadian Medical Device Industry Association
MHLW = Ministry of Health, Labor, and Welfare (Japan)
MIAA = Medical Industry Association of Australia
NEMA = National Electrical Manufacturers Association (USA)
PMDA = Pharmaceuticals and Medical Devices Agency (Japan)
TGA = Therapeutic Goods Administration (Australia)
ZLG = Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (Germany)

** Mr. Shintaro Tobiishi (MHLW) attending meeting as replacement for Mr. Shinichi Takae (MHLW)

2) ACCEPTANCE OF AGENDA

The proposed agenda was accepted as is.

3) REVIEW OF MINUTES FROM LAST MEETING

Egan Cobbold presented the September 30 – October 2, 2007 Washington DC meeting minutes as final. No comments were received from the group.

4) GUIDANCE DOCUMENT SG3(WD)N17 R5 GUIDANCE ON THE CONTROL OF PROCURED PRODUCT AND SUPPLIERS

The text developed by individual members since the Washington meeting were reviewed and incorporated into the body of SG3(WD)N17R7.

The group is considering adding the definition of manufacturer currently under development by the *ad hoc* group lead by SG1 (see GHTF SG1 N55 RXX expected to be ready by March, 2008).

Despite the need for several members of SG3 to take part in joint meetings with other Study Groups and ad hoc groups, significant progress was made over the 3 days on the development of document N17. SG3 now considers the WD of N17 suitable for circulation within the GHTF and will request permission from the SC to circulate it for an abbreviated comment period (30 to 60 days) amongst the regulatory, industry, and technical experts of the other Study Groups for comment. This abbreviated comment period would allow for the compilation of comments in advance of the next scheduled SG3 meeting June 16th – 19th, 2008, as well as facilitate an earlier publication as a proposed document for public comment.

SC decision expected following the Kuala Lumpur meeting (March, 2008).

Member	Action
Egan Cobbold	Submit N17 to Steering Committee by 2008-02-15

5) NEW WORK ITEMS

SG3 was asked by the SC to develop a harmonized guidance on the principles and activities related to regulatory "corrective and preventive action" (CAPA) requirements imposed on medical device manufacturers as part of national or regional regulatory quality management systems (see SG3(NWI)N18).

While in Bonn, a draft framework of what N18 would cover (see attached document N18_mindmap.doc) and a map of the interrelation of the key processes were developed (see attached Visio-N18 .pdf). Volunteers agreed to develop short text on the purpose of the three main sections of the process (as depicted in Visio-N18.pdf). It was agreed that assignments were to be submitted to Carlos Arglebe by March 15, 2008 for compilation. Carlos would then circulate a compiled document to members by April 1, 2008 in advance of the teleconference tentatively set for end of April or beginning of May.

The group started work on this document in October 2007 with the original intent to submit a draft to the SC by the end of 2008. However, the overall timeline for this project must now be adjusted due to the delayed start. Gunter Frey will present this adjusted timeline during the Steering Committee meeting in Kuala Lumpur.

Because of the full agenda for the Bonn meeting, no work on SG3(NWI)N19, QS Deficiencies was performed. Drafting of N19 will commence in June 2008 at the next SG3 meeting. This delay will also affect the overall timeline for development of N19 originally proposed to the SC.

6) REVIEW 5 YR WORK PLAN

The 5 year SG3 2006-2011 work plan accepted by the Steering Committee during the Washington meeting was discussed. Driven by the progress of work during the Bonn meeting, the timeline for the N17 document is expected to be slightly adjusted to accommodate a 90 day or less Stage 3 comment period. The new proposed Stage 7 end date is now tentatively set for the Dec 08.

Member	Action
Egan Cobbold	Update 5 year work plan document for use in Kuala Lumpur
Gunter Frey	Present adjusted time line of work plan in Kuala Lumpur in March, 2008

7) FUTURE MEETINGS

See Item 9 for details of upcoming meetings.

The European Industry representative, Mr Arglebe from Siemens has offered to host the February 2009 SG3 meeting at the Siemens facility in Shanghai, China. Because the joint SG1-SG3 meeting in Bonn was considered to be a great success SG1 has expressed interest in also holding a joint meeting with SG3 in Shanghai. In the event that meeting rooms are not available in Shanghai, the JFMDA members (Mr Nakamura and Mr Asai) offered to host SG3 in either Osaka or Tokyo, Japan.

Member	Action
Carlos Arglebe	Investigate possibility of hosting meeting in Shanghai and report to SG3 Chair
Carlos Arglebe	Investigate ability to participate as trainer at PAHO Training and inform SG3 Chair.

8) OTHER BUSINESS

Proposal to Revise ISO13485:2003
The group discussed at length a proposal submitted by Shigetaka Miura to the GHTF Steering Committee requesting GHTF SG 3 and ISO/TC 210 to hold a joint meeting to revise ISO 13485:2003.

The general consensus of the SG3 members was that there was no need to immediately revise ISO13485:2003 as the points raised in Mr Miura's proposal, particularly that "ISO 13485:2003 is…insufficient to assure product and patient safety. Continual improvement and/or innovation are essential" was not supported by objective evidence.

Although some members acknowledged that ISO 13485:2003 can be improved upon, it was felt that any changes to the standard should be made after the next significant revision of ISO 9001 scheduled for 2015.

It was suggested that the SC approach each of the 5 regulators of the founding member countries with the request to develop an affirmative statement to address that the standards listed in Mr Miura's proposal (ISO14971, ISO9001, ISO14001, and IEC62304) are not direct regulatory requirements, but merely point out a methodology, and that assessment against these standards during an audit should only occur if a manufacturer has chosen to implement them.

Medical Device Interconnectivity ("Plug and Play")
Dr. Carl Wallroth joined the Study Group meeting to present issues regarding interconnectivity of medical devices (plug and play type technologies). Concerns raised include questions around approaches to validation (if change is done to one device, would all connectable devices also need to be validated?, etc.). Issues regulatory in nature are also foreseen, in that the current regulatory regimes for medical devices do not accommodate rapid changes/upgrades (as are daily practice in for instance the software arena).

SG3 suggested that Carl Wallroth submit a position paper on this subject to the Steering Committee and SG3 for review.

Software Ad Hoc Group
On Feb 7, 2008, the Chair and Vice Chair of SG3 were informed that Jos Kraus (Steering Committee member and representative of the ad hoc group for software) requested a meeting with SG3. In order to minimize disruption in the development of the N17 guidance document, the Chair and Vice Chair met with Jos

Jos indicated that the ad hoc group will be in place for approximately 1 more year (to the end of 2008). As such, the Steering Committee wanted to ensure that the study groups continue to be aware of this assistance being available. Mr Kraus was advised that Mr Keith Smith (TGA) has accepted the role as SG3 liaison to the software ad hoc group.

SG3 was encouraged to contact the *ad hoc* group if any questions/request for assistance/guidance come up.

Member	Action
E Cobbold	Draft a written response to Mr Miura's proposal for submission to the SC for their consideration at their March meeting in Kuala Lumpur, Malaysia.

9) CLOSING REMARKS, NEXT SG3 MEETING DATES AND LOCATION (2008)

Meeting Schedule

Date	Host & Location	Purpose
March 3-7, 2008	AHWP, Kuala Lumpur, Malaysia	GHTF SC meeting & AHWP training
End April/beg. May, 2008	Teleconference	SG3 Teleconference
June 16-19, 2008	TGA, Canberra, Australia	SG3 working meeting
October 6-10, 2008	Mexico (City TBD)	GHTF SC meeting & PAHO Training
October 13-16, 2008	Health Canada, Ottawa, Canada	SG3 meeting + Joint SG1, 3 & 4
February 2009	Shanghai, China (alternate Osaka or Tokyo)	SG3 meeting + Joint SG1 & 3
May 2009	Toronto, Canada	Global GHTF conference

**** Submitted February 14, 2008 ****