GHTF SG 3
Meeting Minutes
February 23rd through 27th, 2009
Tokyo, Japan

Location
Hitachi High-Technologies Corporation
24-14, Nishi-Shimbashi 1-chome, Minato-ku,
Tokyo 105-8717, Japan

Meeting objectives:

SG3 Meeting – February 23-26, 2009

1) Continue developing working draft of SG3(WD)N18 CAPA
2) Develop draft objectives and framework for SG3(Draft)N19 QMS deficiencies
3) Group discussion and decision on GHTF - Ad Hoc working Group (Combination Products) proposed work items

Meeting Agenda

	Topic	Representative
1	Welcome and Introductions (apologies/time/safety/lunch/admin support/other)	E Cobbold
2	Acceptance of agenda	All
3	Past meeting minutes • Review draft Ottawa minutes. • Review draft Canberra minutes	All
4	Guidance document SG3(Working Draft)N18 Ottawa R1 *Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes* • Review homework assignments • Develop additional guidance • Prepare Tokyo version	All
	Guidance document SG3(Working Draft) N19 • Refine objective of document • Review Canberra work • Assign work teams to start developing outline of document • Agree on timelines	All
5	AHWG work items	All

	Topic	Representative
	• Combination products (review instructions from AHWG / develop SG3 response / task 2-3 person work group to develop initial response)	
6	Report from Asian Harmonization Working Party (AHWP) activities. • Membership and work of WG3 • Feedback from 13th AHWP Conference , New Delhi, India (Nov 2008)	A Al Dalaan
7	Discussion of joint meetings or Liaisons with : • ISO TC 210/WG1 (see memo from Ed Kimmelman to members of 210/WG1) • ISO TC 176 / SC 2 & SC 3 (?) (revision of 9001 & 19011)	All
8	Future meetings • SG3 teleconference between Ottawa '08 and Tokyo '09. (date and time to be determined) • GHTF Global Conference and SG3 meeting: Toronto, May 10 -15, 2009 • Europe 2009	All
9	Other Business	All
10	Closing remarks	Chair

1) WELCOME AND INTRODUCTION

The Chair of SG3 opened the meeting at 9 am by welcoming members and observers and making the following announcements:

- The joint SG3-SG4 meeting has been cancelled due to SG4 not being able to meet in Tokyo as originally planned.
- Because several regulator members of SG3 were unable to attend SG3's Tokyo meeting the group decided to not work on SG3/N19 during this meeting.
- The Chair asked the members to review and submit comments on *ISO/TC 210 N344 DRAFT INTERNATIONAL STANDARD ISO 13485:2003 TECHNICAL CORRIGENDUM 1, 2009-01-07*
- A meeting of SG3 was proposed for the September/October 2009 timeframe in Ireland to continue work on N18 and N19. Proposed locations are Dublin (at a local hotel) or Galway (at a Medtronic facility).
- Victor Dorman-Smith gave an update on the current views of EUCOMED based on a recent meeting of EUCOMED that he attended. Mr Dorman-Smith reported that the EUCOMED members debated whether EUCOMED should continue its support of GHTF and the outcome of this discussion was that the members were committed to the continued support of GHTF. However, there was strong criticism of GHTF with regard to limiting input and decision

making amongst the original 5 founding members. It is expected that EUCOMED will formally submit a request to the GHTF Steering Committee for a stronger integration of other parties, such as representatives of AHWP, PAHO, etc.

- AHWP representatives Mr. Ali Al Dalaan (Chair AHWP WG3) and Mr Ronald Goon (Vice-Chair AHWP WG3) were formally welcomed to SG3 as permanent members.

In attendance at the Tokyo Study Group 3 meeting were:

Name	Country/ Region	Govt	Industry	Observer	Association
Confirmed					
Al Dalaan, Ali**	Saudi Arabia	X			AHWP
Arglebe, Carlos	EU		X		COCIR
Asai, Hideki	Japan		X		JFMDA
Cobbold, Egan	CAN	X			HC
Dorman-Smith, Victor	EU		X		EUCOMED
Frey, Gunter	USA		X		NEMA
Goon, Ronald	Singapore		X		AHWP
Hirotada, Nagai	Japan	X			MHLW
Kopesky, Ken	USA		X		AdvaMed
Makino, Tsutomu	Japan	X			PMDA
Nakamura, Munehiro	Japan		X		JFMDA
Nicol, Ken	Australia		X		MITA
Okuyama, Noriko	Japan	X			MHLW
Regrets					
Trautman, Kim	USA	X			FDA
Noupbaev Jan	CAN		X		MEDEC
Smith, Keith	Australia	X			TGA
Chan, Tony	USA			TE	
Wetzel, Dirk	EU	X			BfArM
Observers					
Miyamoto, Yuichi	Japan	X		X	PMDA
Janet Welch	USA	X		X	FDA
Hiroshi Kondo	Japan		X	X	JFMDA
Hidemoto Kazama	Japan	X		X	MHLW
Kenji Aoyama	Japan			X	

COCIR = European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
JFMDA = Japan Federation of Medical Devices Associations
HC = Health Canada
EUCOMED = European Association of Medical Device Manufacturers
NEMA = National Electrical Manufacturers Association (USA)
AdvaMed = Advanced Medical Technology Association (USA)
PMDA = Pharmaceuticals and Medical Devices Agency (Japan)
MHLW = Ministry of Health, Labor, and Welfare (Japan)
BfArM = Federal Insitute for Drugs and Medical Devices (Germany)
AHWP = Asia Harmonization Working Party
MEDEC = Canada's Medical Device Technology Companies
TGA = Therapeutics Goods Administration (Australia)

2) ACCEPTANCE OF AGENDA

The agenda was accepted with the following amendments. 1) Deletion of the joint meeting with SG4 because that group did not meet in Tokyo as originally planned; 2) Deletion of item related to work on document N19.

3) REVIEW OF CANBERRA AND OTTAWA MEETING MINUTES.

Canberra (N37) and Ottawa (N38) meeting minutes were approved as presented. The members of SG3 agreed that these documents were now ready to be posted on the SG3 portion of the GHTF website.

Responsible Party	Action Item
EC	Submit Canberra and Ottawa meeting minutes to web administrator for posting on GHTF website.

4) GUIDANCE DOCUMENT SG3(WORKING DRAFT)N18 OTTAWA R1 *QUALITY MANAGEMENT SYSTEM –MEDICAL DEVICES – GUIDANCE ON CORRECTIVE ACTION AND PREVENTIVE ACTION AND RELATED QMS PROCESSES*.

Guidance document SG3(Working Draft) N18:
"Ottawa" home work assignments were integrated into a working draft document called "SG3_N18-prep4Tokyo_R4". This version of N18 was distributed to the SG3 members approximately one week in advance of the meeting.

Work continued in Tokyo on the development of guidance text and supporting graphics. Minor modifications were made to the introduction section to further emphasize the "philosophical" change in use of the term CAPA . Common industry practice is to limit the term CAPA to performing a correction (if applicable) and taking action to "prevent the recurrence" of an identified nonconformity. The actions which are often overlooked are those that should be taken by a manufacturer based on information that is obtained (e.g. trend analysis or evaluation of nonconformities that occurred in a similar product or process) to "prevent the occurrence" of a nonconformity.

Regardless of whether one encounters a non-conformance or a **potential** non-conformance, the process by which these nonconformities are addressed (e.g. the activities associated with both: investigation, root cause, action plan [correction, corrective action, preventive action]) is the same. From a "process perspective" there would be no difference between corrective actions and preventive actions. The content of the record will indicate if an action was corrective or preventive in nature. The acronym CAPA has been commonly used in the medical device industry to describe actions to correct nonconformities and prevent their recurrence. The correct meaning of corrective action and preventive action is defined in ISO 9000:2005, where corrective action is defined as an action to prevent the recurrence of a nonconformity and a preventive action is an action to prevent the occurrence of a nonconformity and this is how these terms are used in ISO13485:2003, Section 8 "Measurement, Analysis and Improvement". Because of the apparent general misunderstanding of

the meaning of CAPA, the study group decided that the acronym CAPA will not be used in the SG3/N18 guidance document in an attempt to not continue the apparent misuse and misinterpretation of CAPA.

A fair amount of discussion arose around the use of the term "management" that is used in Clause 5 of ISO13485:2003 "Management review" as it became evident that the use of the term "management review" was interpreted differently by various members of the study group. The point was made that a type of graduation of nonconformities is applicable to nonconformities and depending on this grading, they are communicated to, and addressed at various levels of an organization. For example, top management or executive management will want to know immediately if a death had occurred involving one of their products, whereas a low level failure of a process would be merely left to be addressed by designated personnel following an established procedure or processes.

During the development of guidance text the group felt that the flow of Figure 1 would be improved if it went from top to bottom which would parallel the flow of the sections in the document. A new graphic in Phase 3 was added to illustrate the possible outcomes of a review and analysis of data points. Dotted lines were added to the right of the flow chart to illustrate that a possible outcome of "management review" would be, were appropriate, fed back to other levels of the organization as a result of actions taken in response to a nonconformity or potential nonconformity.

The outcome of the 3.5 days of work was saved in document "SG3_N18-Tokyo_R5_Day4"

Responsible Party	Action Item
ALL	SG3 members to review document "SG3_N18-Tokyo_R5_Day4" in its entirety to check for proper flow, adequacy and to develop comments for discussion in Toronto. Preliminary comments to be submitted to Chair in advance of March/April teleconference.

5) AHWG WORK ITEMS

No time was available in Tokyo to review the ad hoc working group (AHWG) project related to Combination products. A review of instructions from the AHWG will be performed at a later meeting of SG3.

6) REPORT FROM ASEAN HARMONIZATION WORKING PARTY (AHWP) ACTIVITIES.

Mr. Ali Al Dalaan (Vice Chair AHWP – TC and Chair AHWP WG3) provided an overview of AHWP's work and current developments. There currently are 18 countries represented on WG4, resulting in 25 members of the group. It was pointed out that member countries of ASEAN (Association of South East Asian Nations) has established a uniform regulatory scheme, similar to the European Model. Dr. Pele, although formally retired from his government role, continues to serve as an advisor to AHWP. AHWP's key objectives include becoming a formal regional group under the GHTF, and driving continuous professional development of ASEAN medical device professional under a proposed certification program to be delivered through North Eastern University. The request was made of AHWP-WG3 to provide SG3 with a copy of the curriculum for the proposed regulatory affairs professional certification. Current Chair of AHWP is Wang Baoting

of China.

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Responsible Party	Action Item
Ali Al Dalaan	Share copy of training curriculum with members of SG3

7) DISCUSSION OF JOINT MEETING WITH ISO TC 210/WG1 AND UPDATE OF ISO TC 176 MEETING IN TOKYO, FEBRUARY 2009

ISO TC 210/WG1

Indented text below has been taken from a memo prepared by Ed Kimmelman, Chair WG1 and sent 12 June 2008 to members of TC 210/WG1 for their consideration. I is presented here as background.

> "In 2007, ISO/TC 210 reaffirmed ISO 13485:2003 without change. This was done with the knowledge that the references to ISO 9001 in subclause 0.3.1, Relationship with ISO 9001, will not be accurate once ISO 9001 is amended. In this subclause, reference is made to ISO 9001 with no further reference to the particular version of the standard. Such a reference would indicate the latest version of ISO 9001. When the amended version of ISO 9001 is published in 2009 (ed. actually published in 2008) , the italicized text will not be an accurate reflection of the content in ISO 13485:2003 that is different from the then current ISO 9001 text.
>
> It has been suggested by the management of both TC176 and TC 210 that a corrigendum be developed describing corrections to the ISO 13485:2003 standard to :
>
> • Make the reference to ISO 9001 in subclause 0.3.1 more specific by adding "2000" to the citation.
> • Create a new Annex with a matrix of the differences between 13485:2003 and ISO 9001:2009.
>
> The use of a corrigendum means that a new version of ISO 13485 will not be created and it will remain ISO 13485:2003."

On January 7, 2009 ISO TC 210 published ISO/TC 210 N344 "DRAFT, INTERNATIONAL STANDARD ISO 13485:2003 TECHNICAL CORRIGENDUM" for a 3 month comment period. The Technical Corrigendum uses a chart to describe the text change in ISO 9001:2008 in relationship to the equivalent text in ISO 13485:2003 (if there is such text), the nature of the text change, and a recommended course of action with regard to ISO 13485:2003.

Members of SG3 were asked to review and comment on the draft corrigendum (document N344) in preparation for a SG3 - ISO TC 210/WG1 special teleconference to be held on May 14, 2009 where the following topics will be discussed:

- Review of compilation of comments received on DRAFT ISO 13485:2003, Corrigendum 1
- Update on the ISO/TC 176/SC 2 meeting in Tokyo and plans for future revision of ISO 9001
- Update on resolution of comments received on DRAFT ISO 13485:2003, Corrigendum
- Plans for future revision of either ISO 13485:2003 or ISO/TR 14969:2004.

Update of ISO TC 176 meeting in Tokyo (ISO 9001)
Dr Eamonn Hoxey, Chair of ISO TC 210 attended the ISO TC 176/SC 2 meeting in Tokyo, February 23-27, 2009 as TC210's liaison to TC 176. The following represents a summary of Dr Hoxey's report to TC 210 as well as notes taken by Egan Cobbold who attended the closing Plenary of ISO TC 176/SC2 on February 27.

ISO TC 176/SC 2 has started work on the revision of ISO 9001:2008 by establishing a Task Force to 'consider ideas and concepts for future revision of ISO 9001.' The Secretary of ISO TC 176 SC2, ha indicated that there was no huge pressure to undertake a revision of ISO 9001:2008 and that there was no approved work item in this regard; the discussions in the TC 176/SC 2 Task Group was considered preliminary work as permitted by ISO rules. The next steps that TC 176/SC 2 has agreed to take are:

- conduct a user survey (which would take at least 12 months to prepare issue and analyze),
- look for additional sources of input with regards to 'concepts'
- prepare a Justification Study for approval by ISO TC 176, and
- draft and ballot a New Work Item Proposal.

It was estimated that this process could take up to three years, although some stages might be undertaken in parallel. Preparing a revised text including the various ballot stages would take a further three years. Unless an early systematic review was triggered by ISO TC 176 SC2, a periodic review by ISO would be initiated in 2011. If work on a user survey were initiated shortly, the earliest date that a revised ISO 9001 would be available would be 2015; whereas if the process was initiated following the routine periodic review, the earliest publication of a revised version would be 2018. The shape of any revision would also be influenced by the emerging 'Joint Vision' on Management System Standards (MSS) and the high level common structure/common elements for such standards (see ISO TC 176 SC2 854R).

Dr Hoxey's recommendation to TC 210, which is also applicable to GHTF SG3, is to take note of the following points:

- The potential timescales of any revision of ISO 9001:2008 and the steps involved;
- The opportunity to contribute to any discussions on revision through TC 210's liaison status (which would include GHTF SG3's contribution through the GHTF MOU with TC 210);
- The potential areas that could be considered in any revision.

Responsible Party	Action Item
ALL	Review and comment on document ISO/TC 210 N344 "DRAFT, INTERNATIONAL STANDARD ISO 13485:2003 TECHNICAL CORRIGENDUM"

8) FUTURE MEETINGS

Date	Location	Topic
March/April		Teleconference
May 9 - 12, 2009	Toronto, Canada	3.5 days SG3 meeting
May 12 - 14, 2009	Toronto, Canada	3 days GHTF Conference
May 14 - 17, 2009	Toronto, Canada	3.5 days APEC Training (TBC)
September/October 2009	Europe (Ireland?)	SG3 Meeting (Date and Location TBC)
Fall 2010	Riyadh or Jeddah, Saudi Arabia	GHTF/AHWP joint meeting (Date and Location TBC)

Mr. Ali Al Dalan will inform the group of the outcome of his discussions with Dr. Saleh Altayyar (President of Medical Devices Sector, Saudi Arabia) regarding a possible meeting in Saudi Arabia in 2010. The Saudi Arabian SFDA will host the AHWP and GHTF joint conference, as well as arrange for meeting venues for the GHTF Study Groups.

Responsible Party	Action Item
EC	Provide members and observers of SG3 proposed dates for March/April teleconference

9) OTHER BUSINESS

No other business was discussed.

7) CLOSING REMARKS

The Chair thanked all participants for their attendance and contributions. Gratitude was expressed to Hitachi High-Technologies for graciously hosting this meeting. Special recognition and thanks was expressed to Hideki Asai, Mami-san, and Akemi-san.

**** Submitted March 17, 2009 ****