GHTF SG 3
Meeting Minutes
May 9th through 12th, 2009
Toronto, Canada

Location
Westin Harbour Castle Toronto
1 Harbour Square
Toronto, Ontario M5J 1A6
Canada

Meeting objectives:
SG3 Meeting – May 9 to 12, 2009

1) Continue developing working draft of SG3(WD)N18 CAPA
2) Review objectives and framework for SG3(Draft)N19 QMS deficiencies
3) Prepare for teleconference with ISO TC210/WG 1 on draft ISO 13485:20033 Corrigendum
4) Discuss meeting plans for next 12 months

Meeting Agenda

	Topic	Representative
1	Welcome and Introductions (apologies/time/safety/lunch/admin support/other)	E Cobbold
2	Acceptance of agenda	All
3	• Review and accept draft Tokyo minutes.	All
4	Guidance document SG3(Working Draft)N18 Tokyo R5 *Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes* • Review KK edit • Develop additional guidance • Prepare Toronto version	All
5	Guidance document SG3(Working Draft) N19 • Revisit objective of document	All
6	SG3 update presentation to SC on May 11	All
7	Teleconference with TC 210/WG1 (12:30 @ May 13) : • Teleconference (N342) • ISO TC 210/WG1 (memo from Ed Kimmelman to members of 210/WG1)	All

	Topic	Representative
	• Review Corrigendum (N344) • Review comments (N345)	
8	Future meetings • Location and date of Fall meeting	 All
9	Other Business	All
10	Closing remarks	Chair

1) WELCOME AND INTRODUCTION

The Chair of SG3, E Cobbold opened the meeting at 9 am with logistical comments, and welcome of members and observers. The following announcements were made:

- Japanese regulatory and industry participation in the SG3 meeting as well as the 12th GHTF Conference was cancelled because of concerns relating to the presence of the H1N1 virus (Swineflu) in North America.
- Ms Tokiko Hashimoto will replace Mr Nagai Hirotada as the MHLW (Japanese government) representative on SG3.
- Mr Emmett Devereux (Cook, Ireland) has been nominated by EUCOMED to be the next European/EUCOMED representative on SG3. Mr Devereux will be replacing Dr Victor Dorema-Smith (Abbot, Ireland). To assist in Mr Devereux's transition and integration to SG3 both members have agreed to participate in the Toronto meeting.

In attendance ere:

Name	Country/ Region	Govt	Industry	Association
Attend				
Al Dalaan, Ali	Saudi Arabia	X		AHWP
Arglebe, Carlos	EU		X	COCIR
Cobbold, Egan	CAN	X		HC
Devereux, Emmett	EU		X	EUCOMED
Dorman-Smith, Victor	EU		X	EUCOMED
Frey,Gunter	USA		X	NEMA
Goon, Ronald	Singapore		X	AHWP
Kopesky, Ken	USA		X	AdvaMed
Noupbaev Jan	CAN		X	MEDEC
Smith, Keith	Australia	X		TGA
Trautman, Kim	USA	X		FDA
Wetzel, Dirk	EU	X		BfArM
Regrets				
Asai, Hideki	Japan		X	JFMDA
Hirotada, Nagai	Japan	X		MHLW
Nicols, Ken	Australia		X	MIAA
Makino, Tsutomu	Japan	X		PMDA

Name	Country/ Region	Govt	Industry	Association
Nakamura, Munehiro	Japan		X	JFMDA
Okuyama, Noriko	Japan	X		MHLW
Hashimoto, Tokiko	Japan	X		MHLW
Observer				
John Gams	Canada		X	CAC/TC 210

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 (Japanescalation
MHLW = Ministry of Health, Labor, and Welfare (Japan)
MIAA = Medical Industry Association of Australia
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 formally accepted as proposed.

3) REVIEW OF TOKYO MEETING MINUTES.

Tokyo Meeting minutes were approved by SG3 and will be posted to the GHTF website.

Responsible Party	Action Item
EC	Post Tokyo 2009 Minutes on GHTF web site

4) GUIDANCE DOCUMENT SG3(WORKING DRAFT)N18 TOKYO R5 *QUALITY MANAGEMENT SYSTEM –MEDICAL DEVICES – GUIDANCE ON CORRECTIVE ACTION AND PREVENTIVE ACTION AND RELATED QMS PROCESSES*.

Guidance document SG3(Working Draft) N18:
Saturday May 9, 2009: Work continued on the development of text.

The concept of corrective action and preventive action was discussed. The group agreed that the result of a non-conformance can either be a correction, a corrective action or both. The result of a non-conformance could never be a preventive action, because a non-conformance has occurred and could not be avoided. Even when actions are taken in other parts of an organization (the manufacturer) to address the issue the response is a systemic corrective action.

The acronym CAPA is commonly used in the medical device industry to describe actions to correct nonconformities and prevent their recurrence. The correct meaning of corrective action (CA) and

preventive action (PA) is defined in ISO 9000:2005, where corrective action is defined as an action to prevent the recurrence of nonconformity and a preventive action is an action to prevent the occurrence of nonconformity. This is how these terms are used in ISO13485:2003, Section 8 "Measurement, Analysis and Improvement". Because of the widespread general misunderstanding of the meaning of CA and PA, 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 CA and PA.

It should be emphasized that if an issue is systemically resolved within the same quality management system, it is considered corrective action, even if an issue is identified on one product line and actions are taken on additional product lines.

Sunday May 10, 2009:
The Group agreed to split into several sub-groups to develop chapter specific wording for N18. The Group also agreed to limit discussion on general items by putting them into a "parking lot" located at the end of the Toronto working draft document then review them at a later date after each sub-group had completed their work.

The Group debated the content and meaning of Figure 1 that was developed at the Tokyo meeting. The Group agreed that although monitoring within each data source is expected, this is not made apparent from the graph. In addition, it was agreed that although the improvement phase can be reached after monitoring across data sources, it can also be reached from monitoring within a data source.

It was suggested that a possible 5th box (outcome or path) could exist in Figure 2. This box would show that is possible to use non-conforming product or production materials "as is" (under concession or deviation) without taking any further action like correction, corrective action, preventive action, or escalation into the improvement phase. This scenario would only be envisioned acceptable if the disposition decision is preceded by appropriate investigation into the issue and determination of potential impact (safety, effectiveness, performance, regulatory compliance etc.)

Responsible Party	**Action Items**
KK	Review Section 5, including table and yellow text and provide feedback to Secretary by June 26th
ED	Review Section 6, 6.1, 6.2 and determine if yellow text is appropriate in this section and provide feedback to Secretary by June 26th
KT	Review Section 6.3 and provide feedback to Secretary by June 26th
EC	Review Section 7.4, 7.5 and 7.6 and provide feedback to Secretary by June 26th
KS	Review specifically Section 7.4 and provide feedback to Secretary by June 26th
DW	Review Section 7 and coordinate with KS and provide feedback to Secretary by June 26th
VS	Review information moved to parking lot and attachment A and provide feedback to Secretary by June 26th
ALL	Review entire document and provide feedback to Secretary by June 26th
CA	Compile feedback and provide updated document to SG by August 1st

5) GUIDANCE DOCUMENT SG3(WORKING DRAFT) N19

The Chair summarized the activities performed since the Canberra 2008 meeting.

Keith Smith summarized the reasons why the standard assessment process and principles used in ISO15504 was originally suggested as a model for N19.

The Group decided that the ISO 15504 model was not appropriate as a model for N19 because of its complexity.

A general discussion about the intent of N19 took place and the following points were raised:

- Individual quality system observations or findings do not necessarily constitute a quality system deficiency.
- Work of N19 is limited to a QMS (do not include vigilance reporting, MDR, etc.)
- Need to distinguish between system and product manufactured under the QMS. Significance could then later be based on classification of the product
- Significance of a nonconformity should also be based on safety concerns
- FDA regulations talk to process problems and then tie them to product problems. This is typically not done by auditors and investigators. This can tie into the weighting.
- Some nonconformities are clearly major and some are minor. These are not the difficult ones to judge the significance of. It is the nonconformity that lies between the clear extremes that fall in the middle ground (gray zone) that are a challenge to determine their weighting or significance.
- A criterion that could be used to determine significance could be the repeatability of the same finding.
- There are instances where a regulator and a third party (e.g. Notified Body) might observe and document the same issue but the regulator would classify the finding as significant and the third party would classify it as minor.
- Deficiencies are graded by the auditor, whereas a QMS is graded by a regulator, competent authority, or notified body.
- OMQ/TGA- Australia is the only GHTF regulatory body that has implemented a quality system.
- The next steps in the development of N19 would include standardizing the grading of individual findings. Standardizing would lead to an assessment of the impact of the finding on the product and patient.
- Risk assessments can be done per finding or at a system level and giving consideration to compliance history (or track record) of that manufacturer.
- The topic of consistency of findings is a major issue within the EU. It has been recognized by the commission that the performance of NBs in Europe is not the same. It was mentioned that a European directive has been put into force that every member state should put in place one and only one accreditation body. This will be put into law in Germany, putting the accreditation body into the hands of a non-government entity issuing certifcates, which in turn is accredited by another non-government entity. This may limit direct government agency interventions. The recasting has now been formally postponed, however, there appears to be work going on behind the scenes.
- Could GHTF documents be transposed into MedDev documents?

Dirk Wetzel volunteered to have the German ZLG (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten) documents translated to English.

ZLG documents found at:
http://www.zlg.de/cms.php?PHPSESSID=fcb77c4157f3ca77d5b1f67a23f81511&mapid=102&hmp=6

TGA definitions of a deficiency found on TGA website at:
http://www.tga.gov.au/DOCS/HTML/gmpcldef.htm

Responsible Party	Issue
ALL	Check with Notified Bodies to see if they can provide an approach to grading deficiencies
EC	Contact the 15 CMDCAS auditors to determine if they have definitions of major and minor nonconformities
DW	Provide translation of the EK-MED ZLG 3.5.E11 and 3.9.1.B21

6) SG3 UPDATE PRESENTATION TO SC ON MAY 11

The Chair presented to the Group the updated SG3 2009 through 2011 work plan that he will present to the Steering Committee on May 11, 2009.

The following points were made by members of the Group:

- In order to drive the contents of SG3 guidance documents into ISO standards, future meetings will need to be coordinated with
  - TC 176
  - TC 210 (under existing MoU between TC210 and GHTF; attached below and viewable at http://www.ghtf.org/mou/ghtf-MoU.PDF)
  - AHWP
- The number of GHTF ad hoc projects will continue to increase which might require additional involvement of SG3
- Because the proposed merger of SG3 with SG4 continues to be discussed by the SC, this discussion has created uncertainty as to the future of SG3 and the status of existing work projects
- Add an additional slide to reflect SG3's strategy, including how the developed guidance documents have been or are implemented in countries
- Because of the inconsistency in the outcome of audits/inspections, the work on N19 as well as ISO 9001/13485 is considered important to both regulators and industry.
- The major aspects that need to be considered when revising ISO9001/13485 are supplier controls, risk management, and Corrective Action and Preventive Action.

7) TELECONFERENCE WITH TC 210/WG1 (12:30 @ MAY 13)

Participants in teleconference :

In Toronto, Canada - from SG3, SG4 & SC
Keith Smith
Jan Neaubeav
Victor Dorman-Smith
Dirk Wetzle
Gunter Frey
Kim Trautman
Egan Cobbold
Shigitaka Muira

In New Oreleans, USA - from TC 210
Ed Kimmleman
Hillary Whorle
Eamon Huxley
Harvey Rudolph
Ronald Wichern
Dimitri Nikolaev
Tim Hancox

It was pointed out by SG3 that item 8 of the proposed TC210/WG1 New Orleans agenda was inappropriate and beyond the scope of TC210.

SG3 recommends the acceptance of the Swiss proposal regarding the proposed corrigendum.

Ed Kimmleman was invited to attend the next meeting of SG3 in Limerick Ireland.

The following draft minutes of the Teleconference were prepared by the secretariat of TC 210/WG1.

8) FUTURE MEETINGS

Date	Location	Purpose
September 2nd, 2009 (6am EST/Ottawa)	Teleconference	1 hr SG3 teleconference
September 21 to 24, 2009	Cook Ireland, Limerick, Ireland	4 day SG3 Meeting
January or February 2010	Australia (Sydney or Canberra)	SG3 Meeting (Date and Location TBC)
May or June 2010	United States (Washington?)	SG3 Meeting (Date and Location TBC)
November 2010	Riyadh, Saudi Arabia	GHTF/AHWP joint meeting (Date and Location TBC)

9) OTHER BUSINESS

The GHTF Steering Committee guidance document on the Global Regulatory Model is expected to be published for comment by the end of May, 2009

10) CLOSING REMARKS

The Chair thanked all participants and for their attendance and contributions.

**** Submitted May 30, 2009 ****