GHTF SG 3
Meeting Minutes
October 16-20, 2010
Riyadh, Kingdom of Saudi Arabia

Location
Al Faisaliah Hotel
King Fahad Rd., Olaya,
Riyadh, KSA

Meeting objectives:
1) Continue design and development of SG3(Draft)N19: QMS deficiencies

Meeting Agenda

	Topic
1	Welcome and Introductions (apologies/time/safety/lunch/admin support/other) • Introduction of new permanent members, technical experts & observers
2	Acceptance of agenda
3	Review and accept minutes from September 16, 2010 teleconference. Review action items from Teleconference
4	Guidance document SG3(Working Draft) N19 • Continue design and development activities
5	Feedback from SC Teleconference meeting in August 2010 and other items of interest Status of N18 CAPA Status of ISO 13485 ad hoc group Status of ISO TMB decision on the high level structure for all MS standards
6	Update on work of AHWP
7	Other Business Development of an SG3 position paper on the revision of ISO 13485 that all members can use when communicating with stakeholders.
8	Closing remarks

1) Welcome and Introductions

The Chair opened the meeting at 9 am on October 16 by welcoming all members and observers and thanking the Saudi Food and Drug Authority (SFDA) for hosting the meeting.

Mr A Al Dalaan, SG3's AHWP member and SFDA host, also welcomed everyone to Riyadh and introduced the SFDA team that had volunteered to assist SG3 while in Riyadh. On behalf of Dr Saleh Al Tayyar, Vice Executive President for Medical Devices Sector, SFDA, Mr Al Dalaan invited the SG3 members and observers to visit on October 18 the current SFDA premises and to briefly meet with the President of the SFDA and other SFDA staff. Purpose of the visit was to learn about the interim Saudi Medical Devices regulations and the plan to eventually replace the interim regulations with a final medical device regulatory framework.

Attendees: Ali al Dalaan, Hideki Asai, E Cobbold, Emmett Devereux, Gunter Frey, Ron Goon, Kenichi Ishibashi, Munehiro Nakamura, Taishi Nakashima, Dirk Wetzel

Observers: Rania El Asmar, Victor Dorman-Smith, Steve McRoberts, Julie Runge, Takashi Hiura

Regrets: Carlos Arglebe, Laila Gurney, Ken Nicol, Scott Sardeson, Keith Smith, Kim Trautman

2) ACCEPTANCE OF AGENDA

The agenda was accepted with the addition of an item under "other business" calling for the group to develop a position paper on the revision of ISO 13485:2003.

3) REVIEW AND ACCEPTANCE OF MINUTES FROM THE SEPTEMBER 16, 2010 TELECONFERENCE

The group agreed that formal minutes of the September 16 teleconference were not needed since it was limited to: 1) a status check of work items relating to N19 that would be needed for the Riyadh meeting; 2) share information on the status of the work of ISO TC 176; and 3) update the group on the status of SG3 guidance document N19 following the SC August teleconference. Action items arising out of the teleconference related solely to travel issues related to the Riyadh meeting.

4) GUIDANCE DOCUMENT SG3(WORKING DRAFT) N19

Significant progress was made on the development of draft guidance for document N19. The work output of the meeting on October 20 is called N19 Day 5.

Key accomplishments at the Riyadh meeting include:

a) Development of a process flow chart to illustrate steps that an auditing organization or manufacturer could take to analyse a finding, determine its significance, and then rate it based on a yet to be developed grading system. (Grading system to be developed at next face-to-face meeting)
b) Development of a rating table based on the Japanese rating model that groups a finding into one of four groups (called score in document) ranging from whether the finding is not a nonconformity (group 1 or score 1) up to nonconformity that represents absence or failure of a core process and/or it relates to safety, effectiveness, or performance problems of a device (group 4 or score 4).

c) Identification and definition of words and terms that will, or may be, used in N19 and ensuring that these definitions are consistent with existing GHTF and ISO definitions.
d) Selection of several examples of findings taken from a larger set of examples relating to an internal audit of a manufacturer and an FDA inspection. Performed an initial assessment of this selection of examples by applying the draft "significance rating decision tree" to them in order to determine the "significance" group they would fall in. That is group/score 1, 2, 3 or 4. Rating the examples also allowed the group to verify the suitability of the rating tree and to determine if improvements to the wording used in the tree were needed. Selection of examples placed in Attachment 1 of draft "N19-day 5".

At the end of the meeting the following action items were identified and assigned to members for completion by 2011-03-15. Completed action items will be used at SG3's next face-to-face meeting in Tokyo, April 2011.

Action Item 4 -1: (Dirk, Emmett & Steve)
Develop definition of the term "regulatory requirement" or review and adopt current definition of regulatory requirement as found in GHTF SG4 N28.

Action Item 4 -2: (Victor)
Check day 5 version of N19 to ensure the proper and consistent use of key words and phrases like nonconformity, QMS vs quality management system, finding, etc.

Action Item 4 -3: (Steve)
Develop or complete definitions given in section 4 of N19.

Action Item 4 -4: (Steve)
Send electronic version of work flow diagram in Viso format to Egan by 2011-03-15.

Action Item 4 -5: (Steve)
Refine or revise working version of "significance" decision tree. Send visio version of decision tree to Egan by 2011-03-15.

Action Item 4 -6: (Julie & Victor)
Review section 5 of N19-day 5 to see if some of the text should be placed in the Introduction section. (Julie to perform review following Victor's completion of item 4-2)

Action Item 4 -7: (Emmett)
Develop text of section 6.1 so that it matches flow chart.

Action Item 4 -8: (Egan)
Develop text that introduces the "significance" decision tree in section 6.1

Action Item 4 -9: (Dirk)
Develop text of section 6.2 so that it matches flow chart.

Action Item 4 -10: (Gunter)
Develop text of section 6.3 so that it matches flow chart.

Action Item 4 -11: (Ron, Julie, Steve & Gunter)
Using existing models used by Julie and Gunter, develop the concept of the "report card" that will be used to grade the finding in the context of N19.

Action Item 4 -12: (Hideki, Mune, Takashi, Kenichi, Taishi)
Review selected examples and verify that:

a) text in example is clear and informative;
b) text is consistent with guidance in N19; and
c) each example contains enough introductory text so as not to force the reader to make uninformed assumptions or guesses to justify the ratings given in the example. Ratings must be supported by clear evidence in the description of the finding.

5) FEEDBACK FROM SC TELECONFERENCE MEETING IN AUGUST 2010 & OTHER ITEMS OF INTEREST

a) Status of N18 CAPA
The chair reported that the GHTF SC will make a final decision on the acceptance of document N18 as a Final document at the November 2010 face-to-face meeting of the Steering Committee.

b) Status of ISO 13485 ad hoc group
The chair reported that there was no news to report on the work of the GHTF SC ad hoc group on ISO 13485.

c) Status of ISO TMB decision on the high level structure for all MS standards
The chair reported that the ISO TMB has delayed any decision on the work of the TMB joint technical coordinating group relating to the adoption of a common high level structure and text for all management system standards.

7 UPDATE ON WORK OF AHWP

R Goon reported on the outcome of the AHWP that he attended in Taiwan, September 2010. He shared his presentation with the group. See attached.

8) OTHER BUSINESS

The members prepared a common position paper on the future revision of ISO 13485:2003. It is expected that SG3 members will use this common position when commenting on the revision of ISO 13485:2003.

All SG members at the Riyadh meeting agreed in principle to hold a joint face to face meeting with AHWP WG3 sometime in late 2011 either as part of the proposed September meeting in France or at another time and location that would be convenient to both SG3 and WG3. The purpose of the meeting would be to allow AHWP WG3 to actively participate in the final drafting of N19. Details of this joint meeting will be developed further in the months ahead.

9) FUTURE MEETINGS

WHEN	WHERE	WHAT
April 11-12, 2011	Tokyo, Japan	Joint GHTF SG3 – TC 210/WG1
April 13- 15, 2011	Tokyo, Japan	GHTF SG3 meeting (hosted by JFMDA/Hitachi)

WHEN	WHERE	WHAT
September TBD, 2011	Buc, France (TBC)	SG3 meeting (hosted by GE Healthcare)

CLOSING REMARKS

The Chair thanked all participants for their attendance and contributions. Gratitude was expressed to SFDA for graciously hosting the meeting. Special recognition and thanks was expressed to T Al Ghamdi, M Alamer, A Alsaeed, H Bagaib, M Al Dohan, A Al Gifari, M Al Ismaiel, A Al Shareef, H Al Rashed, A Al Watban and countless others from SFDA for their generous hospitality, behind the scenes support, and translation assistance that allowed the Riyadh meeting to be productive and a great success.

February 17, 2011 Addendum to Riyadh meeting minutes

On November 10 V Dorman-Smith circulated to the members of SG3 an updated version of N19 Day 5 and called it N19 Day5Rev. This version contains consistent use of the terms QMS and nonconformity(ies) and corrected spelling and grammatical mistakes. No content was changed. Following the circulation of version “Day 5Rev” consensus was reached on the use of several important terms. It was agreed that to be consistent with current ISO terminology used in 19011, 9000 and other documents the following words would be used in N19:

- audit findings - Clause 3.4 " results of the evaluation of the collected audit evidence against audit criteria"
- audit evidence - Clause 3.3 "records, statements of fact or other information, which are relevant to the audit criteria and verifiable"
- audit criteria - Clause 3.2 "set of policies, procedures or requirements"
- audit finding is a post-audit activity that is the outcome of evaluating audit evidence. Audit findings may be that of a conformity, or a nonconformity, with requirements.
- In the practice of auditing an auditor is gathering audit evidence in relation to a potential nonconformity (for some auditors, or in some situations, may also be a gathering of evidence of conformity). An auditor may observe a situation, however what is written down / recorded has to be evidence that will later, after evaluation, support findings; whether or not those findings are determined to be a conformity, or nonconformity, with requirements.
- The ISO9001 Auditing Practice Group (see Guidance on documenting a nonconformity) strongly discourages the use of the term "observation" as it has connotations of an "opportunity for improvement" or "recommendation".
- ISO term "audit evidence" will be used instead of the word “observations" because it is a neutral term and does not imply if the evidence is for a conformity or a nonconformity.
- The ISO 9000 term (Clause 3.6.2) "nonconformity" will be used rather than “deficiency” when referring to the "non-fulfilment of a requirement"
- "auditee organisation" will be used as it removes any ambiguity and is likely to align with future releases of ISO19011.