# GHTF SG 3
# Meeting Minutes
# October 15 to 17, 2008
# Ottawa, Canada

**Location**
Lord Elgin Hotel
100 Elgin Street
Ottawa, Ontario
Canada

**Meeting objectives:**

**SG3 Meeting – October 15 – 17, 2008**
1) Review public comments on Draft document SG3(PD)N17R7: *Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers*. Revise version N17R7 and prepare a final version for submission to the Steering Committee by mid-December 2008 for their endorsement and approval to publish in February 2009 as a Final GHTF document.
2) Review status of Canberra homework assignments of SG3(Draft)N18 CAPA.
3) Meet with SG1 and SG4 to discuss Work Items of mutual concern

**Joint SG3 & SG4 Meeting – October 17, 2008**
Discuss Work items of mutual concern

## Meeting Agenda

### Topic

1 Welcome and Introductions (apologies/time/safety/lunch/admin support/other)

2 Acceptance of agenda

3 Review working draft version of Canberra minutes. Note that portions of the minutes are missing. These sections will be completed at or after Ottawa meeting.

4 Guidance Document SG3(PD)N17 R7
*Guidance on the control of procured product and suppliers*
- Review compiled public comments. Focus will be on Technical comments.
- Prepare Final version of SG3N17 and submit to the SC for endorsement (Stage 6)
- Revised document must be submitted no later than 8 weeks in advance of February 26, 2009 SC meeting. Target date for submission to SC is mid-December 2008.

5 Guidance Document SG3(DRAFT)N18 Canberra R1 *Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes*
- Review status of homework assignments
- If time permits, prepare "Ottawa R2 version" of N18

6 Discussion of joint meetings or Liaisons with :
- ISO TC 210/WG1 (see memo from Ed Kimmelman to members of 210/WG1)
- CASCO
- ISO TC 176 / SC 2 & SC 3 (?) (revision of ISO 9001 & 19011)

7 Update of SG3 work plans presented to GHTF Steering Committee October 7, 2008.

8 Future meetings
- SG3 Meeting: Tokyo February 23- 27, 2009 (Location: Hitachi High-Tech Building)
- 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

9 Other Business
- Joint meeting with SG4 on October 17, 2008
- Draft response to Software Ad Hoc Working Group's memo to SC and SG3.

10 Closing remarks

## 1) WELCOME AND INTRODUCTION

The Chair of SG3 opened the meeting at 8:30 am by welcoming members and observers and made the following announcements:

- The Steering Committee has asked for a volunteer from each Study Group to participate in developing a formal GHTF endorsed training materials. Training would be delivered through professional organizations such as RAPS (Regulatory Affairs Professional Society). Interested members were asked to confirm there interest via an e-mail to the Chair by October 24.
- The Chair informed SG3 members that the discussion and final decision on a merger of SG3 and SG4 has been postponed until May 2009. Until a final decision is made, both Study Groups were asked to continue carrying out their existing work plans.
- Mr Carlos Arglebe has agreed to formally perform the role as SG3's secretary. His role will be reflected on the GHTF web site.
- Time will be set aside during the 4 days so that the group could prepare a draft response to the Software AHWP's memo to the SC and SG3 received October 16, 2008 relating to recommendations on the referencing of software in existing and future GHTF guidance documents.

Attendees at the Ottawa Study Group 3 meeting were:

| Name | Country/ Region | Govt | Industry | Observer | Association |
|---|---|---|---|---|---|
| Al Dalaan, Ali | Saudi Arabia | X | | X | AHWP |
| Arglebe, Carlos | EU (Germany) | | X | | COCIR |
| Cobbold, Egan | Canada | X | | | HC |
| Dorman-Smith, Victor | EU (Ireland) | | X | | EUCOMED |
| Frey, Gunter | USA | | X | | NEMA |
| Kopesky, Ken | USA | | X | | AdvaMed |
| Makino, Tsutomu | Japan | X | | | PMDA |
| Nakamura, Munehiro | Japan | | X | | JFMDA |
| Noupbaev, Jan | Canada | | X | | MEDEC |
| Okuyama, Noriko | Japan | X | | | MHLW |
| Trautman, Kim | USA | X | | | FDA |
| Wetzel, Dirk | EU (Germany) | X | | | BfArM |

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)

## 2) ACCEPTANCE OF AGENDA

The proposed agenda was modified with the inclusion of the following topics under Item 9 : i) Hold a Joint SG3 and SG4 meeting, on Friday October 17; and ii) Draft a group memo in response to the Software AHWP's memo to the SC and SG3 received October 16, 2008.

## 3) REVIEW WORKING DRAFT VERSION OF CANBERRA MINUTES

Time did not allow for a formal review of the draft Canberra minutes by the group. The Chair and Vice chair agreed to complete these minutes then circulate to the group for their review before the next meeting in February 2009.

| Responsible Party | Issue |
|---|---|
| EC + GF | Update draft Canberra meeting minutes and circulate to SG3 members prior to February 2009 meeting. |

## 4) GUIDANCE DOCUMENT SG3(PD)N17 R7 *GUIDANCE ON THE CONTROL OF PROCURED PRODUCT AND SUPPLIERS* : REVIEW OF PUBLIC COMMENTS

Fourteen separate submissions containing approximately 120 lines of comments were submitted to SG3 by September 15, 2008. Comments were collated and characterized as either "technical" or "editorial" by Ken Kopesky in advance of the October meeting. To optimize the use of meeting time, all "technical" comments were reviewed first followed by "editorial" comments. All comments were either accepted in whole, in part with an explanation, or rejected. The disposition of each comment was recorded and the text of version R7 amended to reflect the group's decision. The output of the review process was a document that would be suitable for submission to the SC for their review and acceptance as a Final document.

A lengthy discussion arose around the inclusion of a proposed table (line 84 of compiled comments) to be used in the evaluation of a supplier's ability to detect non-conformities/defects and the corresponding control measures manufacturers may need to consider. The members of SG3 ultimately concluded that inclusion of the proposed table would not be beneficial at this time as its contents were deemed to be incomplete.

Since all comments were considered during the meeting and all study group members were satisfied with the output of the review process, unanimous agreement was reached to submit version SG3N17/R9 to the GHTF Steering Committee by Monday, October 20, 2008. The SC will be asked to review and approve version R9 for publication as a Final document and to provide SG3 with a response following the December 11, 2008 Steering Committee teleconference.

| Responsible Party | Issue |
|---|---|
| EC | Submit SG3N17/R9 to the Steering Committee by no later than Monday, October 20, 2008 (Action completed) |

## 5) GUIDANCE DOCUMENT SG3(DRAFT)N18 CANBERRA R1 QUALITY MANAGEMENT SYSTEM –MEDICAL DEVICES – GUIDANCE ON CORRECTIVE ACTION AND PREVENTIVE ACTION AND RELATED QMS PROCESSES

Very little progress was made on the development of this document during the Ottawa meeting. The amended version, called SG3(DRAFT)N18 Ottawa R2, will be circulated to the Study Group members in order for them to complete any outstanding homework assignments. Work instructions are included in the document. Assignments are to be submitted to the Secretary by January 16, 2009 for overall incorporation into the document.

| Responsible Party | Issue |
|---|---|
| All Members | Complete homework assignments based on work instructions in N18 Ottawa R2 and submit to Carlos A by January 16, 2009. |
| CA | Incorporate all homework assignments into body of the document and submit to Chair and Vice Chair by February 6th, 2009. Secretary to increase revision number to reflect addition of work assignments. |

## 6) DISCUSSION OF JOINT MEETINGS OR LIAISONS WITH ISO TC 210/WG1, CASCO, AND ISO TC 176 / SC 2 & SC 3

The Group held a general discussion relating to the need for the GHTF to develop liaison relationships with ISO TC 176/ SC2 and SC3, and the ISO Committee for Conformity Assessment (CASCO).

All members of SG3 were in favour of GHTF developing a liaison with CASCO. All members were also in favour of continuing the existing Memorandum of Understanding (MOU) between GHTF and ISO TC 210 because this is the technical committee that is responsible for the development of ISO 13485 and ISO/TR 14969. It is also via this arrangement that SG3 can significantly participate and contribute to the development of international medical device related standards. By working with TC 210 and its liaison status with ISO TC 176, GHTF SG3 will be able to get involved at an early stage in any future work that ISO TC 176 will undertake on the development of the 201X generation of ISO 9001.

## 7) UPDATE OF SG3 WORKPLANS PRESENTED TO STEERING COMMITTEE OCTOBER 7

The members were advised that on October 7, 2008 the Steering Committee was briefed by the Chair on the current work status and challenges of SG3's work items. The Steering Committee was advised that no new work items relating specifically to product software and combination products (pharmaceutical- device combinations, biologics-device combination, etc.) could be undertaken at this time by SG3 primarily because of the groups existing workload. In addition, it is felt that in order to develop meaningful guidance for these specific topics, input from subject matter experts in these areas would be required before any work could be started.

## 8) FUTURE MEETINGS

| Date | Location | Reason |
|---|---|---|
| February 23 - 27, 2009 | Tokyo, Japan | 4 days SG3;<br>1 day joint SG3/SG4 meeting |
| May 10 - 12, 2009 | Toronto, Canada | 2.5 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 | Issue |
|---|---|
| AAD | Confirm meeting dates and location for Fall 2010 meetings with Dr. Saleh Altayyar and report back to SG3 Chair and Vice Chair. |
| VDS | Confirm meeting dates and location for September/October SG3 meeting and report back to SG3 Chair and Vice Chair. |

## 9) OTHER BUSINESS

SG3 and SG4 met jointly on October 17, 2008 in Ottawa.
The purpose was to update members of both groups on current status and progress of common work items.

a) SG4's N84 – Auditing manufacturer's control of suppliers
b) Update to SG4 on progress of SG3's N17 document
c) Merger of SG3 and SG4
d) Update on ISO13485
e) Joint SG3/SG4 meeting in Tokyo

**SG4/N84**
SG4's approach to writing N84 "Auditing manufacturer's control of suppliers" will be based on the flowchart provided in SG3/N17, with emphasis on the types of objective evidence an auditor may expect to examine.

It was pointed out that from an auditing perspective it would be irrelevant if a supplier is external or internal to a manufacturer (as defined in SG1(PD)/N055R6), as one would be looking for the same type of objective evidence to establish that adequate controls are in place.

SG4 clarified that the right hand side of the flowchart in SG3/N17 “Examples of Objective Evidence” will be taken into consideration when completing the work on their SG4/N84 document. As when auditing these aspects of a manufacturer, the audit strategy should most likely begin with selected suppliers and the controls around those, rather than focusing on how suppliers were selected (planning, although important, is secondary to the controls from an auditing perspective).

**Joint meeting**
SG3 will meet for 4 days in Tokyo, beginning February 23rd. The chair of SG4, in accord with the members of SG4 agreed to meet in Tokyo at the same time. This would facilitate a joint meeting, should the need arise. However, it was pointed out by SG3 that as we get closer to the meeting date and should there be a joint meeting that an agenda be published in advance.

**Merger**
The Chair of SG3 updated both study groups on the current status of the proposal to merge SG3 and SG4. Comments from members of both study groups indicated that neither study group is in favor of a merger. The Chair of SG3 informed the groups that the Steering Committee’s discussion on a merger SG3 and SG4 has been postponed until May 2009. Until this discussion is finalized, both Study Groups were asked to continue executing their existing work plans.

**Update on ISO13485:2003**
The Chair of SG3 provided an update on the developments around this standard. Although this is a stand-alone standard, it is closely aligned with ISO9001. Due to the recent activities of ISO TC 176 to revise ISO9001, ISO13485:2003 is also considered for possible revision. This work would occur within ISO TC 210 with participation from SG3 under the 1999 MOU.

**Response to AHWG - Software memo**
A draft response to the AHWP-Software was developed by the group and will be submitted to the Chair of the AHWG-Software as soon as possible. The key points of the response are:
i) The members of SG3 recommend that the existing ISO/TC 210 – GHTF MOU SG3 be used to support the development of a Technical Report for validation of the application of computer software for production and service provision.

ii) That this recommendation be forwarded to IEC/ISO JWG2, because it understood that this group is currently working on a guidance document related to the subject of medical device software.

(note: Bullet 11 of the minutes of the Bangkok, Thailand ISO TC210 meeting from October 19th, 2007, the secretary of IEC/SC 62A noted that “IEC/ISO JWG2 continue work on the guidance document on ISO14971 and ISO13485 (IEC/TR 80002, Medical device software – Guidance on the application of iSO14971 to medical device software). A Committee Draft was expected to be issued in early 2008.”

## 7) CLOSING REMARKS

The Chair thanked all participants for their attendance and contributions.

**** Submitted November 18, 2008 ****