

GHTF SG3 – Malvern, PA
April 13-15th, 2011

Attendees:

Ali Al Dalaan
Carlos Arglebe
Egan Cobbold
Victor Dorman-Smith
Emmett Devereux
Akie Yamashita
Kenichi Ishibashi
Kim Trautman
Scott Sardeson
Rainer Edelhaeuser
Minehiro Nakamura
Asai Hideki
Emmet Deveraueux
Gunter Frey (by phone)

Observers/Technical Experts:

Julie Runge
Sandra Brolin

Regrets:

Keith Smith
Ken Nicols
Ron Goon
Steve McRoberts

1. ADMINISTRATIVE:

The meeting minutes from the teleconference on February 17, 2011 were accepted

Minutes from last meeting are not posted on GHTF website. There have been several meetings since last upload.

ACTION ITEM – Egan update the GHTF website with the meeting minutes
(Completed May 9, 2011)

New membership: Rainer Edelhaeuser has joined as the new EU regulatory representative replacing Dirk.

ACTION ITEM – Membership list on GHTF website needs to be updated everyone to send contact information to Egan in format from GHTF website (GHTF website updated May 9, 2011)

2. FUTURE MEETINGS:

- 1) June 20, 2011 -Teleconference to review work assignments.
- 2) Oct 2011 - Develop working draft of N19. Buc, France GE Healthcare to host – **Action Laila Gurney**
- 3) March 2012 (i) Joint TC210/SG3 meeting and (ii) closed door SG3 meeting - At joint meeting continue work on revision to ISO 13485. At SG3 closed door meeting complete a working draft of N19.

TC210 WG1 will be meeting in fall with a Plenary. It will be good for any SG3 folks that can attend this meeting to do so. Location will probably be US West Coast

3. AHWP Update

Ali Aldaan provided an updated from AHWP. AWHP has accepted N17. AHWP membership is expanding. Total is 27 countries now. Next global meeting will be in Bali the first week in Nov 2011. The next meeting of AHWP will be in July 2011.

4. ITEMS FROM THE JOINT MEETING WITH TC210

Several folks had difficulty in the TC210 meeting since we did not have all the documentation. Egan had sent many recent documents but several documents being referred to were only available to the ISO committee members. For future meetings it is important we have the same information. However we have to make sure we obtain access correctly. Individuals should check with their national TAG or affiliation. In addition Egan will do his best to forward relevant information. He will also inquire with Hillary if there is a way to get direct access to TC210 work area only. It is important to make sure we do this correctly. According to MOU the SG3 chair is the link to WG1 so Egan may have to just be our contact to all documents.

TC176 update from Kim – Jan Welch and Ken Nicol attended. Still working on concepts and do not have a work proposal approved. Some delay is due to the survey not getting enough survey responses. Next meeting will be in China. There may be a desire to have a SG3 representative attend if possible. K Nicol has volunteered to attend the meeting in China if his work travel plans take him to China at the same time.

5. FUTURE SC MEETING IN BRISBANE:

GHTF SC will meet in Brisbane, Australia during May 2011. It is important to give them an updated our SG3's liaison work with ISO TC210 this week. **ACTION ITEM Egan** – Prepare and submit a revised update to the SC for Brisbane meeting in May. Add TC 210 items and review dates for N19 – COMPLETED. Sent to Larry Kelly for inclusion in the Brisbane agenda.

WORK ITEM N19:

The “4 square” tool or matrix was developed after many different reiterations on how best to represent a grading. The group decided that the matrix would be used as a screening tool to give a base rating to finding. Additional rules could be applied to the base rating to elevate the significance of a finding. The group felt that this approach was a better way than a flowchart to determine a rating of a finding. There was a brief discussion to expand the matrix to 6 cells or more but the group felt this approach would be too complicated.

HOMEWORK AND FUTURE ACTION ITEMS:

Teleconference in June before EC goes on leave.

Revise Process Flowchart and text outline for this section of N19. Address multiple findings, repeats and absence of process: Scott and Julie before the TC

Revise Matrix and Link the title of the matrix to the scope -Carlos

Review the definitions - Victor

Work on the Audit Finding Table (Format and how to complete): Kim

Format

How to complete

Parking lot

- How do we use this in industry, internal audit, day-by-day issues, input to the CAPA
- How to use the tool for other issues like trends that input to CAPA