

SG3 / N25R0

**GHTF SG 3
Meeting Minutes
October 31st to November 2nd, 2006
Osaka, Japan**

Location:

Kaneka Corporation

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1) WELCOME AND INTRODUCTION

E Cobbold (Chair SG3) opened the meeting at 9:15am by thanking the representatives of Kaneka Corporation and JFMDA for arranging meeting accommodations. Apologies for those unable to attend were made. Present members briefly introduced themselves.

No new members or guest experts attended the meeting. The following represents a summary of the meeting.

SG3 members in attendance were:

Name	Country/Region	Government	Industry	Consultant	Association	Attended
Asai, Hideki	Japan		X		JFMDA	Y
Cobbold, Egan	CAN	X			HC	Y
Dorman-Smith, Victor	EU		X		EUCOMED	Y
Frey, Gunter	USA		X		NEMA	Y
Gams, John	CAN			X	MEDEC	Y
Kopesky, Ken	USA		X		AdvaMed	N
Nakamura, Munehiro	Japan		X		JFMDA	Y
Nicol, Ken	AUS		X		MIAA	Y
Schoenbuehler, Werner	EU		X		COCIR	Y
Smith, Keith	AUS	X			TGA	N
Trautman, Kim	USA	X			FDA	N
Yamamoto, Junji	Japan	X			PMDA	Y
12		4	7	1		9

Observers: Mr. Masaaki Tsukano (Compliance and Narcotics Division, MHLW), Mr. Yuichi Miyamoto (QMS Audit Division of PMDA), Mr. Kazuaki Sanaka (Quality Supervisor, Kaneka Corporation).

2) ACCEPTANCE OF AGENDA

The agenda was accepted with modification. J Gams requested the addition of a discussion of coordination/harmonization of ISO 13485 and ISO 9001 (SG3 with TC210 and TC176).

3) REVIEW OF MINUTES FROM LAST MEETING

E Cobbold reviewed the last meeting minutes (SG3N22R1) and was accepted by the group. A comment was made that the meeting dates for the 2007 GHF Conference now been finalized for October 3-4, 2007. (Note: as of January 18, 2007 the conference dates, including the SC meeting, SG meetings and Conference have now been set for September 31 to October 5, 2007 .)

4) UPDATE ON JOINT PROJECTS WITH OTHER STUDY GROUPS

a) J Gams provided an update on his involvement with the Compilation of Definitions document. Mr. Gams compiled definitions from published GHF SG3 documents and provided this list to Ishikawa-san. This exercise illustrated that multiple definitions exist for a number of terms. As of this Osaka meeting Ishikawa-san has not commented on SG3's contribution. SG3 assigned document control number SG3N27R0 to the list of SG3 terms submitted to Ishikawa-san.

The document was reviewed by the Study Group and determined that no further work was required by the group.

b) E Cobbold presented to the study group the SG1 NWI proposal regarding the definition of manufacturer.

The Study Group decided that SG3 will work with SG1 on this work item proposal.

5) NEW SG3 WORK ITEMS

5.1 NWIPS SUBMITTED TO STEERING COMMITTEE

On October 11, 2006 E Cobbold submitted electronic versions of the following three New Work Item Proposals to the Steering Committee secretariat for presentation at the Steering Committee's Brussels, November 29-30, 2006 meeting. Following a lengthy discussion by the SG members of each NWIP a course of action for each NWIP was decided upon.

- a. **CAPA Guidance Document:** From regulatory inspections and audits, Corrective Action and Preventive Action (CAPA) remains one of the most frequently cited issues. Also, from FDA experience on the topic post-market indicators (e.g. Warning Letters, Medical Device Reports [MDRs], Recalls, Vigilance Reporting, etc.) appear to be trending upward. These data points may suggest a lack of understanding of CAPA principles. New Work Item Proposal: Quality Management System - Guidance on Corrective and Preventive Action (CAPA) principles and activities. Priority: Of the 3 proposed NWIs, this should be advanced with the highest priority

Timetable:

November 2006 – Brussels - Approval of NWIP by SC

February 2007 to May 2007 - SG3 perform literature review/gather information. Start developing Working Draft

May 2007 – Los Angeles – Continue developing Working Draft at SG3 meeting

September 2007 – Washington – Continue developing Working Draft at SG3 meeting

February 2008 – Location TBD – Bring to Proposed Document stage at SG3 meeting

June 2008 - Proposed Document ready for review by SC

The work done by W Schoenbuehler regarding Supplier CAPA can serve as a good starting point and along with the NWIP is attached below:

- b. **Quality System deficiencies:** Interpretation of quality system deficiencies varies amongst regulators. *New Work Item Proposal: Quality Management System - Guidance on the significance of quality system deficiencies*

Significant discussion arose around this topic. Issues at hand range from variation amongst auditors within regulatory bodies and third parties, variation in interpretation of the same issue by various regulatory bodies, etc. The Study Group felt that any guidance that might be presented in this document might be philosophical in nature rather than presenting best practices. The Study Group felt that the work associated with this NWIP will be significant and that more analysis of the topic and what the expected outcome is required. Further analysis by the group before a timeframe can be defined. The Study Group recommended that until further analysis has been performed on the subject that this NWIP be withdrawn from the SC for their consideration as a new work item.

- c. **Quality Plan:** ISO document on quality planning FDIS10005:2005. Some initial work was done earlier by GHTF, however this has not been completed. *Consider review of work done so far by GHTF regarding quality plans and submit recommendation to Steering Committee*

This item requires further analysis by the group before a timeframe can be defined. The Study Group recommended that until further analysis has been performed on the subject that this NWIP be withdrawn from the SC for their consideration as a new work item.

In summary, the members of SG3 decided to continue working on document SG3N17 (Guidance on the management of procured products, outsourced processes and their suppliers) so that it may be presented to the Steering Committee in time for their May 2007 meeting in Los Angeles.

The new work item proposal SG3(NWI)N18 (CAPA) is considered highest priority as the next project for the SG to begin work on. SG3(NWI)N19 and SG3(NWI)N20 will be reviewed again by the group at the February 2007 meeting of SG3 and are currently considered long range projects. The group suggested that approval of these two work items by the SC will not be sought at this time, but rather SG3 will inform the committee that further research into these complex topics is required and SG3 will resubmit to the SC at a later date. W Schoenbuehler will represent SG3 at the Brussels SC meeting.

5.2 SG3 PARTICIPATION AT NOVEMBER 2006 GHTF STEERING COMMITTEE MEETING, BRUSSELS

Due to scheduling conflicts the Chair and Vice-Chair are unable to attend the November 2006 SC meeting. W Schoenbuehler, a member of the SC and of SG3 has agreed to represent SG3 at the SC meeting. In addition to presentation of SG3's current and future work activities, W Schoenbuehler will raise the point that a European Regulatory representative on SG3 is needed in order to rebalance the European regulator/industry membership.

6) ADMINISTRATIVE ISSUES

- a) Verification of information on SG3 website (names, titles, addresses, phone, e-mail, affiliations):

All members attending the Osaka meeting reviewed and updated a paper copy of the membership list that is presently on the GHTF website. G Frey will provide the GHTF webmaster with this information.

- b) Work plan (topics, timelines)

The Chair will develop and circulate to the group for review/comment a revised work plan for SG3 based on discussions at the Osaka meetings. Members are asked to review this and provide feedback to the Chair. G Frey is to initiate updates to the website.

- c) Schedule of meetings and participation (SC, SG3, ISO TC 210/WG1, joint SG meetings)

Study Group 3 Meetings:

SG3 Ottawa, February 21 – 23, 2007 (Health Canada facilities)

SG3 Los Angeles, May 9- 11, 2007 (FDA facilities)

SG3 Washington, DC, September 30 - October 2, 2007 (Ronald Reagan Building and International Trade Center)

Joint SG meetings:

Time and place to be determined. Discussion on joint SG Meetings will need to be held with G Michoud (Chair SG1) and M Zobrist (Chair SG4).

Steering Committee Meetings:

SC, Brussels, November 29 – 30, 2006 (European Commission facilities)
SC, Los Angeles, May 7-8, 2007 (date to be confirmed)
SC Washington, DC, October 1 – 2, 2007 (Ronald Reagan Building and International Trade Center)

11th GHTF conference & Advamed Global Conference:

Washington DC, October 3 - 5, 2007 (Ronald Reagan and International Trade Center)

Annual TC 210 meeting:

ISO TC 210, Thailand, October 15 – 19, 2007 (Plenary October 19th)

ISO TC 210 WG1, Thailand, October 15 & 16, 2007

7A) EXPLANATION OF PROPOSAL TO INCLUDE IN ISO13485:2003 MORE DETAILED ACTIVITIES OF RISK MANAGEMENT

Asai-san provided further details and background information on the proposal submitted by JFMDA. This proposal (see attachment below) will be submitted to the SC as a position paper only. The proposal is not intended to “raise the bar”, but rather requests the incorporation of key risk management elements (i.e. Risk analysis including hazard identification, risk evaluation, risk control and measures for residual risk) into the next version of ISO13485:2003.

It appears as if the confusion referred to in the JFMDA proposal is based on a number of factors:

- ISO13485:2003 was re-written in Japan as a regulation
- this regulation now makes reference to ISO14971 as a note only (ISO 14971 is not a regulation nor is it a regulatory document).
- Only a single sentence in the Japanese Ministerial Ordinance refers to Risk management activities.
- Lastly, some portions of the Japanese QMS ordinance are exempted from implementation until spring of 2007 under the transition period.

For reasons of avoiding redundancy ISO13485 deliberately included generic references to risk management activities and limited reference to ISO14971 as an informative reference only.

SG4's N30 guidance documents includes details of risk management activities , as auditing necessarily covers specific aspects of risk management activities.

SG3's position regarding this topic has already been made public through it's response to JWG1 N124 position paper. SG3's position is found in document SG3N18R1, which was presented to TC210 JWG1 at the annual meeting of TC210 in Paris in April of 2006.

A number of SG3 members felt that the concerns raised within the JFMDA proposal may be best addressed by the Japanese government (MHLW) developing and publishing a specific guidance document for Japan regarding risk management activities.

7B) COORDINATION / HARMONIZATION OF 13485 AND 9001 (ISO TC 210 AND TC 176)

E Cobbold (SG3 Chair) will contact H Woehrle (Secretariat of ISO TC 210) and E Kimmelman (Chair ISO TC 210/WG1) to arrange for a joint SG3 and ISO TC 210 JWG1 meeting in either May or September 2007 to address current developments around the revision of ISO 9001.

Depending on the outcome of discussions between SG3 and TC210 WG1 on ISO 13485, SG3 may in 2007 have to become more active in the discussion and drafting of any amendments to ISO 13485:2003 and ISO/TR 14969:2004 based on expected amendment to ISO 9001:2000 that is scheduled to take place in the next 1 to 2 years.

Representation of SG3 may be required at the next meeting of ISO TC 210 WG1 October 15 and 16, 2007.

K Nicol offered to route to the chair and vice-chair requests from Standards Australia for comments on proposed standards. The chair or vice-chair will circulate to SG3 members for their information.

8) CONTINUATION OF WORK ON GUIDANCE DOCUMENT SG3(WD)N17 SG3 GUIDANCE ON THE CONTROL OF PROCURED PRODUCT AND SUPPLIERS

SG3 continued drafting SG3(WD)N17. The plan is to complete this document in Ottawa (February 2007) and bring it to the stage of proposed document followed by submission to the Steering Committee in 2007.

The proposed section 5.5 “Analysis of supplier process or product” has been deleted and incorporated into section 5.2 Supplier Evaluation. Section 5.2 expanded to address Supplier Qualification.

9) OTHER BUSINESS

No other business to discuss.

10) CLOSING REMARKS

SG3 wishes to thank Mr. M Nakamura and Mr. K Sanaka for hosting a successful and productive meeting. SG3 also wishes to thank Kaneka Corporation for providing the meeting rooms and JFMDA for the hospitality extended to SG3 during the course of this meeting.

The next meeting is scheduled for February 21 – 23, 2006 in Ottawa, Canada

The meeting adjourned at 5:30 pm on November 2nd, 2006.