



**GHTF SG 3
Meeting Summary
June 25-28, 2006
Lübeck, Germany**

SG3 / N23

Location:

Draeger Medical,
Moislinger Allee 53-55,
D - 23548, Lübeck,
Germany

Agenda :

- 1 . Welcome and Introduction
 2. Presentation to the Lübeck, June Steering Committee Meeting
 3. Proposed Outsourcing Guidance document – Review of study group members contribution and drafting
 4. Consolidation of next meeting dates
 5. AOB
- Adjournment

Participants:

12 members and 3 observers. (7 Government, 8 Industry)

1) WELCOME AND INTRODUCTION

Alain Prat (SG3 Chair) opened the meeting at 9am with logistical comments, followed by introductions. No new members or guest experts attended this meeting. The following represents an unofficial summary of the meeting.

2) PRESENTATION TO THE LUBECK JUNE STEERING COMMITTEE MEETING

Alain Prat presented to the members of SG3 a draft of the presentation that he will deliver to the GHTF Steering Committee sometime during the SC meeting of June 25 -27, 2006. The presentation highlighted the recently completed work of SG3, present work activities and direction for future topics/activities.

**3) PROPOSED OUTSOURCING GUIDANCE DOCUMENT – REVIEW OF STUDY
GROUP MEMBERS CONTRIBUTION AND DRAFTING**

Drafting continued on the SG3(WD)N17 document (Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers).

Significant discussion arose around how to conceptually structure the document due to the complexity of the topic, diversity of the industry covered and unique business models used by device manufacturers.

The output of the 3.5day guidance development activity is version R2 of the document. Time did not permit the development of all sections of N17R2 so most members were assigned work items that called for the submission of draft text to the chair by September 15, 2006. The Chair will consolidate all submissions then redistribute a single document to the SG members 2 weeks before the October 31 -November 2, 2006 Osaka meeting.

4) CONSOLIDATION OF NEXT MEETING DATES

Based on upcoming Steering Committee meeting dates and a desired completion date of mid-2007 for draft of SG3N17 (Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers) SG3 meeting dates were tentatively scheduled as follows:

October 31 – November 2, 2006	SG3 meeting: Osaka, Japan
November 28 – 30, 2006	Steering Committee meeting: Brussels
January/February, 2007	SG3 meeting: Ottawa, Canada
May 7-8, 2007	Steering Committee meeting: Los Angeles
May 9-11, 2007	SG3 meeting: Los Angeles, USA
September, 2007	SG3 meeting: Washington, USA

5) AOB

Long term work items for SG3

The principle mission of Study Group 3 is to identify common quality system aspects and requirements and to develop harmonized guidance based on global regulatory requirements. Further, SG3 engages in activities in support of maintaining harmonized requirements.

During the Lübeck meeting, SG3 developed a long-term view/strategy for the study group. The strategy involves i) the continuation of SG's present liaison activities with ISO TC 210 *Quality management systems and corresponding general aspects for medical devices*; ii) the completion of present or deferred work items; and iii) the development of new guidance documents on quality system related topics that are of concern to the regulatory and industry members of SG3.

Copies of the following new work item proposals will be submitted to the Steering Committee for their information and consideration at least eight weeks in advance of the next SC meeting scheduled for November 28-30, 2006.

Guidance on harmonized requirements:

- a. **Completion of SG3N17:** (Guidance on the management of procured products, outsourced processes and their suppliers) draft by February, 2007 (in time for Los Angeles SC meeting in May). *This is continuation of New Work Item Proposal SG3N16.*
- b. **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 perspective, 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.*
- c. **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*
- d. **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.*

Activities in support of maintaining harmonized requirements:

- e. **Future revisions to ISO13485:2003 based on future revisions to ISO9001:2000.** The automotive industry has asked for more detail to be included in future version of ISO 9001 on topics such as Failure Mode Effects Analysis (FMEA), Risk Management, tool descriptions. TC210 is scheduled to meet in Bangkok, Thailand, October 15-19, 2007. SG3 participation is desired and advisable. Most recently TC 176/SC2 met June 19-23, 2006 in Tralee, Ireland where working groups of TC176/SC2 meet to progress the development of an amendment to ISO 9001:2000 and a revision to ISO 9004:2000. The next meeting of TC176/SC2 is scheduled for November 13-17, 2006 in Busan, Korea.
- f. **Update to ISO13485** (based on minor interim update to ISO9001:2000 possibly by 2008) All activities are to be performed according to the terms of the GHTF-TC210 Memorandum of Understanding.
- g. **Update to TR14969** (as a result of updates and revisions to ISO13485:2003) Activity carried out under terms of MOU with TC210. Technical Reports are valid for 3 years, and can be amended/extended for an additional 3 years. After this time, it either needs to be converted to an ISO standard or withdrawn. As TR14969 provides valuable guidance but conversion to a standard is not appropriate, the GHTF should consider converting this document into a GHTF guidance document.
- h. **Maintain liaison with TC210:** ongoing activity (MOU with TC 210 is open ended).
- i. **Seek information from regulators on quality management system areas/topics that would benefit from guidance.** Work began on Process Validation, Design Validation as a result of being approached by regulators. Create an open-ended list of topics facilitating global harmonization based on feedback from regulators/industry/trade associations (e.g. AHWP, NEMA, US FDA, Health Canada, Japanese Ministry of Health, Labor and Welfare, Australia TGA, AdvaMed, JFMDA, EU, etc.).
- j. **Joint SG meetings:** Regular joint study group meetings are proposed.

6) CLOSING REMARKS

SG3 wishes to thank Alain Prat for his chairmanship of SG3 – As of the Lübeck meeting Alain has resigned as Chair of SG3 due to his appointment to the World Health Organization (WHO).

SG3 wishes to thank Draeger Medical for providing the meeting rooms and for hosting a successful and productive meeting.

Mr. Egan Cobbold of Health Canada has been confirmed by the Steering Committee as the new Chair of SG3.

Following a motion for the appointment of a Vice-Chair/Secretary for the SG, the Chair proposed that Mr. Gunter Frey, representing a US industry sector (NEMA), be assigned the dual role of Vice-Chair/Secretary. The motion was unanimously passed.

The meeting adjourned at 11:30 am on June 28, 2006.

Respectfully submitted this 13^h day of July, 2006

******* The next meeting is scheduled for October 31- November 2, 2006 in Osaka, Japan *******