GHTF SG 3
Meeting Minutes
June 16-19, 2008
Canberra, Australia

Location

Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

Meeting objectives:

1. Develop first Working Draft of SG3(WD)N18: Quality management system – Medical devices - Guidance on Corrective and Preventive Action (CAPA) Principles and activities.
2. Members of "regulatory" working group brainstorm on objectives of SG3N19 QS Deficiencies.
3. Develop SG3 position on proposed merger of SG3 and SG4.

Meeting Agenda

	Topic	Representative
1	Welcome and Introduction (apologies/time/safety/lunch/admin support/other)	E Cobbold K. Smith
2	Acceptance of agenda	All
3	Guidance Document SG3(WD)N18 Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activities. A. Review current industry thinking (see attached reprints) B. Review homework assignments C. Develop working draft D. Assign work items for next meeting	All
4	Guidance document SG3 (WD)N19 Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies.	E Cobbold K Smith K Trautman N Okuyama Y Miamoto
5	Other Business • Proposal to merge SG3 and SG4. • Pros and cons of merger • Structure of merger	All
6	Future meetings A. GHTF training in Mexico October, 8-10, 2008 (2 industry volunteers needed as trainers) A. Ottawa, Joint SG1, 3 & 4 meeting, October 14-17 B. Shanghai, SG3 meeting, early January, 2009 C. Toronto, GHTF Conference, May 2009 D. Europe, SG3 meeting, October 2009?	All
7	Closing remarks A. Date and location of next meeting	E Cobbold

1) WELCOME AND INTRODUCTION

E Cobbold, Chair SG3, opened the meeting at 9:15 am with logistical comments, and welcome of members and observers. Dr. Mark Doverty (Head, Office of Manufacturing Quality, TGA) welcomed SG3 members on behalf of TGA.
In attendance were:

Name	Country/ Region	Govt	Industry	Observer	Association
Arglebe, Carlos	EU		X		COCIR
Asai, Hideki	Japan		X		JFMDA
Cobbold, Egan	CAN	X			HC
Dorman-Smith, Victor	EU		X		EUCOMED
Frey, Gunter	USA		X		NEMA
Kopesky, Ken	USA		X		AdvaMed
Nakamura, Munehiro	Japan		X		JFMDA
Nicol, Ken	AUS		X		MTAA
Smith, Keith	AUS	X			TGA
Trautman, Kim	USA	X			FDA
Okuyama, Ms. Noriko (replaceing Akiko Hayashi)	Japan	X		replacement	MHLW
Miyamoto Yuichi	Japan	X			PMDA
Chan, Tony	USA			X	U Virginia, (Tech Exprt)

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)
MTAA = Medical Technology Association of Australia
TGA = Therapeutic Goods Administration (Australia)
MHLW = Ministry of Health, Labour, and Welfare (Japan)
BfArM = Federal Institute for Drugs and Medical Devices (Germany)
ZLG = Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (Germany)
EUROM 6 = European Industrial Federation – Medical Technology

2) ACCEPTANCE OF AGENDA

The Chair presented the proposed agenda. It was accepted with addition of a topic to discuss the TC210/WG1 proposal of revision of ISO13485:2003 to include further details around risk management activities.

3) GUIDANCE DOCUMENT SG3(WD)N18 QUALITY MANAGEMENT SYSTEM – MEDICAL DEVICES- GUIDANCE ON CORRECTIVE AND PREVENTIVE ACTION (CAPA) PRINCIPLES AND ACTIVITIES.

During the course of developing text for this guidance document, significant discussion arose around the use of the term “CAPA” or “Corrective Action and Preventive Action”. Strong arguments were made by industry and regulators that not all issues identified within the quality system require “CAPA” – some may not even get to that level, but rather be addressed exclusively with corrections. There are business processes (as defined within the manufacturer’s Quality Management System) which allow for

monitoring and trending. For example, non-conforming parts may be scrapped unless certain thresholds (financial, quantity, safety, etc.) are reached.

Arguments were also presented, supporting the need to include in the data analysis activity (once a threshold or action level has been reached) a review across various appropriate data sources to ensure actions are taken at all appropriate points. The Study Group members felt that thresholds should be defined that are based upon objective criteria rather than randomly defined (Note: justification/rationale for all defined thresholds should be documented). Significant discussion continued on the extent of guidance that would be needed on the data sources, the type of data within the data sources, trigger points, and other related topics.

Of note is that regulators argued (and ultimately supported by industry) that the concept of "corrective action and preventive action" may not be appropriate in all cases. For example, actions taken in response to a trend, such as Statistical Process Control (SPC) charting, has typically been termed "preventive action", whereas current thinking may more appropriately term such activity as process controls.

4) GUIDANCE DOCUMENT SG3 (WD)N19 QUALITY MANAGEMENT SYSTEM – MEDICAL DEVICES - CRITERIA FOR CHARACTERIZING THE SIGNIFICANCE OF QUALITY MANAGEMENT SYSTEM DEFICIENCIES.

The regulatory members of SG3 met separate from industry to discuss common issues relating to characterizing the significance of quality management system deficiencies. The regulatory members agreed to provide their definitions of a non-conformity used within their respective regulatory framework. TGA presented a model used in the software sector that may potentially lend itself to characterizing the significance of quality management system deficiencies in a more consistent matter amongst regulators and within industry.

5) OTHER BUSINESS

During the course of this meeting the Chair briefed the members of SG3 on the Steering Committee's recent discussions (June 18 teleconference) around the proposal of merging SG3 and SG4. The Steering Committee postponed final decision on this proposal until the May 2009 Steering Committee meeting.

Study Group 3 is opposed to the merger of these two Study Groups in the near term (i.e. before completion of SG3's existing 2006 to 2011 work plan). This position is based on a number of reasons, not the least of which will be a lack of available experts following a merger to develop guidance relating to Quality Management System requirements and the auditing of Quality Management Systems for compliance with such requirements. These subject areas are distinct and require subject matter experts to develop meaningful guidance documents. Moreover, by merging the two groups, SG3 feels that the effective membership of the combined group would be reduced without regard to amending existing workloads and work plans. SG3 feels that a merger would ultimately lead to a significant delay in the completion of existing work items and proposed work items.

Furthermore, it is unclear to the members of SG3 how a merger of SG3 and SG4 would be structured with regards to leadership, membership, regional representation and meeting schedules.

Considering that the both SG3 and SG4 membership is larger than 15 members and that both groups typically meet 3 times per year for 4 days, a merger of the groups would result in only 3 meetings per year for up to 4 days, which would result in less work being accomplished.

From a cost perspective, it would appear that the cost of completing all existing work items would not be reduced, but would instead be spread over a longer period of time, potentially keeping valuable guidance document from being made available in a timely manner.

6) FUTURE MEETINGS

October 14 – 17, 2008	Health Canada, Ottawa, Canada	(1+3 days), SG4/SG3/SG1 joint meeting, Lord Elgin Hotel
February 2009	Tokyo, Japan	(3-5 days), SG3/ SG4 joint meeting
May, 2009	Toronto, Canada	(3 days) SG3 meeting, GHTF Conf.
September/October 2009	Europe	SG3 Meeting - TBC

7) CLOSING REMARKS

The Chair thanked the TGA for hosting the meeting of SG3 at the TGA facilities. The Chair also thanked the members, observers and technical experts for their attendance and contributions.

**** Submitted December 16, 2008 ****