GHTF SG 3
Final- Meeting Minutes
June 7 to 11, 2010
Los Angeles, California, USA

Location
3M Unitek
2724 South Peck Road
Monrovia California, USA 91016

Meeting objectives:
1) Review public comments on SG3(PD)N18 CAPA and prepare a Final version suitable for submission to SC
2) Continue design and development of SG3(Draft)N19 QMS deficiencies

Meeting Agenda

	Topic
1	Welcome and Introductions (apologies/time/safety/lunch/admin support/other) • Introduction of new permanent members, technical experts & observers
2	Acceptance of agenda
3	• Review and accept minutes from April 8, 2010 teleconference. • Review action items from Teleconference
4	SG3(PD)N18 • Review public comments • Prepare Final version of SG3 N18
5	Guidance document SG3(Working Draft) N19 • Continue design and development activities
6	Feedback from SC meeting in Singapore May 10, 2010 • SC ad hoc group on ISO 13485 • New Chair for SG1 • Other …
7	Update on work of AHWP
8	Other Business
	Closing remarks

1) WELCOME AND INTRODUCTION

The Chair opened the meeting at 9 am with logistical comments and welcome of members and observers.

S Sardeson gave a 20 minute presentation about the history of 3M and the company's involvement in the medical device sector. Following the presentation 3M employees Ms Anne Wu and Mr Cisco Nuño gave the members a 30 minute guided tour of the 3M Unitek manufacturing facility.

Attendees: Carlos Arglebe, Hideki Asai, E Cobbold, Ali al Dalaan, Emmett Devereux, Ron Goon, Laila Gurney, Kenichi Ishibashi, Taishi Nakashima, M Nakamura, Scott Sardeson, Dirk Wetzel, Kim Trautman,

Observers: Victor Dorman-Smith, Hidetaka Hokao, Jerry Horn, Steve McRoberts, Julie Runge, Holly Seppanen

Regrets: Gunter Frey (available by phone / webex for 1.5 days), Ken Nicol, Keith Smith

> **Action Item 1-1:** E Cobbold to update GHTF SG3 website with new member's name and titles.

2) ACCEPTANCE OF AGENDA

The agenda was formally accepted with the addition of an item for E Cobbold and K Trautman to update the group on the work of ISO TC 176 on the revision to ISO 9001:2000. The update was performed under "Other Business".

3) REVIEW AND ACCEPT MINUTES FROM APRIL 8, 2010 TELECONFERENCE

The draft April 8, 2010 teleconference minutes were accepted as is. All action items were completed.

> **Action Item 3-1** : E Cobbold to arrange to have teleconference minutes posted to GHTF website.

4 N18: Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes

Approximately 100 lines of public comments regarding the Proposed Draft version of N18 were reviewed. Changes were made to the draft text as appropriate. Where comments were not accepted, reasons were documented and will be provided to the commenter.

> **Action Item 4-1:** E Cobbold to provide feedback to those who submitted comments on PD N18.

> **Action Item 4-2:** Members are to review the final document by July 9th and provide E Cobbold with any additional comments. E Cobbold will submit the final document to the Steering Committee for the August 27th t-con. (Action completed. Final document submitted to SC on July 9, 2010)

5) BRAINSTORMING ON COMPOSITION OF N19 – QUALITY MANAGEMENT SYSTEM – MEDICAL DEVICES - CRITERIA FOR CHARACTERIZING THE SIGNIFICANCE OF QUALITY MANAGEMENT SYSTEM DEFICIENCIES

The scope and intent of the document was reviewed then the Group brainstormed around developing a tool (Matrix) that could be used to rate the significance of nonconformities and the QMS audit as a whole. The group decided on a 4-point scale for assessment of risk where 1 is considered non-significant and 4 significant. A matrix was proposed and K Trautman, S McRoberts, S Sardeson and J Runge were tasked with providing the team members with a list of sanitized non-conformities to rate according to the matrix.

The team will rate the non-conformances according to the matrix for a teleconference to be scheduled for September 16th. The outcome of this teleconference will be used to help develop a first draft of the N19 guidance document at the meeting in Riyadh in October.

To further illustrate the utility of a 4-point scale, the group conducted a "brainstorming" exercise (aka KJ Exercise) to develop examples of deficiencies related to QMS topics "documentation" and "implementation of documents". Members identified four observations or fact that they considered to be deficiencies related to a QMS documentation requirement or the implementation of that QMS document. All deficiencies were allocated by the members into one of four "groups" depending on the member's expert opinion on the significance of the deficiency in relation to the QMS requirement. The output of the KJ exercise is in attachment 1.

Action Item 5-1: K Trautman, S McRoberts, S Sardeson, J Runge to provide a list of sanitized non-conformities to rate according to the matrix by September 2nd
Action Item 5-2: From the list of QMS processes provided by S McRoberts members are to score their top 10 with Xs.
Action Item 5-3: At the October meeting members are to take the examples that are provided in Item 5-2 then : 1) identify the nonconformity; 2) identify the process it belongs to from UL's list; and 3) grade the nonconformity from 1-4 (4 being the worse) under documented and implemented
Action Item 5-4: E Devereux, C Arglebe and D Wetzel to improve the LA version of N19 for use at the September teleconference/webex

6 FEEDBACK FROM SC MEETING IN SINGAPORE MAY 10, 2010 RE: 1) SC AD HOC GROUP ON ISO 13485 AND 2) NEW CHAIR FOR SG1

E Cobbold gave a brief update on the work of the SC ad hoc group on the "improvement of ISO 13485". All SG3 members felt that SG3 should prepare a memo for the SC highlighting the work that SG3 has done with ISO TC 210 and the need for SG3 to continue its work with ISO TC 210/WG1. The memo was also to present a strategy for the revision of ISO 13485:2003 based on events currently taking place at ISO at the Technical Management Board (TMB) level and by the SC ad hoc group, lead by Dr Neumann, on the "improvement of ISO 13485". The members of SG3 felt very strongly that any future revision to ISO 13485 must be carried out according to the mandate that SG3 has been given by the SC on this subject as well as any agreements the GHTF has established with ISO and its various technical committees like TC176.

The memo was to be sent to the Chair of the SC and the member of the ad hoc group as soon as possible.

It was announced at the Singapore meeting that Dr Ginette Michaud (FDA) was stepping down as Chairperson of SG1 and will be replaced by Ms Nancy Shadeed (HC) as the new Chairperson of SG1.

> **Action 8-1 :** E Cobbold to send memo to Steering Committee and CC all members of SG3. (Action completed. Memo sent July 14, 2010)

7 UPDATE ON WORK OF AHWP

A Dalaan gave an update on the work of the AHWP WP3. He informed the group that the Saudi FDA will be hosting an AHWP conference in Riyadh December 4 to 8, 2010. The members of SG3 are invited to attend the conference. D Wetzel volunteered to attend the meeting as an SG3 representative and to give an update on the work of SG3.

> **Action 7-1 :** E Cobbold to send a memo to Dirk Wetzel inviting him to speak on behalf of SG3 at AHWP meeting (Action completed. Memo sent June 18, 2010)

8) OTHER BUSINESS

Members invited to comment on SG1's guidance document on definition of medical device. Documents and request for comments e-mailed to SG3 members on June 1, 2010.

> **Action 8-1 :** Members to submit comments on SG1 guidance document to A Kent by September 17, 2010.

9) FUTURE MEETINGS

WHEN	WHERE	WHAT
September 16, 2010	Webex/Teleconference	GE(Canada) to host 1 hr teleconference. Start time TBD
October 6-20, 2010	Riyadh, Saudi Arabia	GHTF SG3 meeting (hosted by SFDA)
April 11-12, 2011	Tokyo, Japan	Joint GHTF SG3 – TC 210/WG1
April 13- TBD, 2011	Tokyo, Japan	GHTF SG3 meeting (hosted by JFMDA/Hitachi)
September TBD, 2011	Buc, France	SG3 meeting (hosted by GE)

Action 9 -1: L Gurney to organize t-con / webex for **September 16th** .

Action 9-2: E Cobbold to send request to E Kimmelman and H Woehrle for joint meeting with TC210 WG1. (Action completed. Teleconference bwtween EC, EK, EH and HW held July 28, 2010 and agreement reached for a joint SG3/TC210 WG1 meeting in Tokyo April 11&12, 2011)
Action 9-3: A Hadiki to send request to JFMDA to host joint meeting between SG3 and TC210 in April 2011.
Action 9-4: T-con will be scheduled between Saudi and Japan – date to be determined in Saudi.

CLOSING REMARKS

The Chair thanked all participants for their attendance and contributions. Gratitude was expressed to 3M Unitek for graciously hosting the meeting. Special recognition and thanks was expressed to Vicki Skidmore for her administrative support.

**** Submitted August 27, 2010 ****

Attachment 1
N19 Deficiencies KJ Exercise

Topic	1	2	3	4
Documentation	• IFU Colour of binder out of spec • Process requirement documented • Traceability of document • Perfectly controlled • Regulatory requirements documented • Well documented and followed • Detailed sterilization procedure approved and in place • Full implementation inc all definition and responsibilities documented	• Calibration records do not include statement of traceabilty to NIST <u>Revision control</u> • Procedure is obsolete • QM out of date • Revision has not been correctly done • There is no revision control on procedure • No dated • No revision number • Document is not controlled • No history record • No tracecability • Revision control • Wrong document control number • Uncontrolled documents • IFU version number wrong <u>Approval</u> • No approval by relevant key approvers • Documents are not reviewed • Procedure exists but not approved by required functions • Internal audit not signed off • QM Manual not signed • Detailed sterilization procedure in	<u>Awareness</u> • Uncontrolled document on shop floor • No signed by appropriate manager • Not available in all languages required by users • No copies on site for calibration performed by external firm • No awareness of document but document does exist <u>Implementation</u> • Documents are reviewed but not followed the SOP • Not available at point of use • Procedure does not reflect actual process • Detailed procedure in place but non critical steps not carried out as documented • Procedure does not outline roles and responsibilities • There are no justifications for not to validate <u>Document Clarity</u> • Unclear instructions • White out and record keeping • Record with missing data elements	<u>No procedure</u> • No procedure at all • No documented procedure at all • No procedure • No procedure documented • No documentation procedure or rule • No incoming inspection records • No records of process parameters of sterilization • No documents • No content • Procedure does not exist • No sterilization documentation in place • Internal audit not documented • No QM • No medical device operation and control documentation <u>Requirement</u> • Procedure does not address/reference regulatory requirements • Pre-filled records **<u>Parking Lot</u>** • **No IFU for device** • **No intended use in IFU**

Topic	1	2	3	4
		place but missing some minor sign offs	• Record clearly documents "out of specification" or Outside acceptance criteria" with no justification for acceptance • Record only "Pass" for measured inspection • Procedure is in conflict with other procedural aspects on timelines • Procedure that use terminology such as "When appropriate" or "When needed"	
Implementation	• Sterilisation procedure fully documented, followed and fully meets all requirements • Packing of device with accessories with wrong accessories in 0.5% of shipments • QM not available on site • Procedure is consistently applied meeting requirements with all required records. No anomalies detected • Perfectly implemented according to the procedure • Implemented completely • Training complete and effective	• Procedure mostly applied well with isolated anomalies • Implemented but a little differently from the procedure • Implemented but not consistent • Management not available for audit • Records are created but are not kept well. Some records are lost • Employee contradicts procedure • No training schedule for the year • Training programme does not include effectiveness evaluation • Sterilisation procedure fully documented, not fully followed by	• Quality objects are not revised for 5 years • 50% of internal audits not performed • Electronic record keeping is not validated • Procedure understood by some operators • Implemented but significantly different from the procedure • Sterilisation procedure fully documented, not fully followed or used by operators and no process issues • Calibration not performed over range of use • Training complete but not effective – several issues • Process not followed completely –	• Procedure does not address key measuring stages of a process leading to out of specification product • CAPA was not reported to Top Management • No management review record • 50% of products not clean • No implementation • Procedure exists but there was no user training – so it is not implemented • Only a subset of users are trained – so procedure is not consistently/always implemented • Change in critical process manufacturing condition (e.g. speed or temperature) not validated • 50% of incoming inspection not performed • Failure investigation not finding root cause

Topic	1	2	3	4
		all but no process issues • The contents of management review are not fully covered • Training occurs after procedure implemented	optional requirement • Process followed completely but training not documented • Procedure documented but no procedure at point of use • Process measuring does not address key risks of the process • Procedure written but not followed correctly	• Only one site oot of a 4 site organization uses procedure • Computer system used to prevent release of non-conforming material is not validated • Procedure written but operators not trained • Risk analysis tools utilized to justify taking no actions versus pre-determined trigger point or action levels • Major design input specification not verified or validated • Process not followed completely – mandatory requirement • Lack of implementation cause recall or field action • Sterilization procedure fully documented, procedure not understood or followed, numerous issues • No implementation • Checklist not implemented