



11th GHTF Conference

Washington, D.C., USA

October 3-4, 2007

Study Group 3 - Quality Systems: Status Report

**Egan Cobbold
Chair SG3**

overview of report

our role ...

membership...

what we've done so far...

barriers to implementation...

what we plan to do in the near future...



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

our role ...

“SG3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization.”

www.gh tf.org/sg3/sg3.htm



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

membership...

Australia

Mr Ken Nicol

Mr Keith Smith

MIAA/St. Jude

TGA/MAB

Canada

Mr Egan Cobbold

Mr Jan Noupbaev

HC/MDB (Chair of SG3)

MEDEC/Medtronic Can.



SG3

11th GHTF Conference

Washington DC, October 3-4, 2007

membership...

European Union

Mr Carlos Arglebe*	COCIR/Siemens
Mr Victor Dorman-Smith	EUCOMED
Mr Dirk Wetzels*	EU/BfArM (Germany)

(* after May 2007)

Japan

Mr Hideki Asai	JFMDA/Hitachi
Mr Munehiro Nakamura	JFMDA/Kaneka
Mr Masaaki Tsukano**	MHLW
Mr Junji Yamaoto**	PMDA

(** up to July/2007)



SG3

11th GHTF Conference
Washington DC, October 3-4, 2007

membership...

United States of America

Ms Kimberly Trautman	FDA1
Mr Gunter Frey	NEMA/GE (V-Chair/Sec)
Mr Ken Kopesky	AdvaMed/Medtronic



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

membership...

Regulatory reps.	6
Industry reps.	8
Observers	1 – 2 (upon request)
Technical experts	1 – 2 (when invited)



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we've done so far...

Since 1992, the study group has prepared and published four guidance documents. Two are “final” and two have been “archived” because their contents were transferred to ISO/TR 14969:2004

Final Documents

SG3/N99-10 (Edition 2) Quality Management Systems - Process Validation Guidance.

SG3/N15R8/2005 Implementation of Risk Management Principles and Activities Within a Quality Management System

Archived Documents

GHTF.SG3.N99-8 Guidance On Quality Systems For The Design And Manufacture Of Medical Devices

GHTF.SG3.N99-9 Design Control Guidance For Medical Device Manufacturers



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we've done so far...

Since 1992, the study group has worked in partnership with ISO TC 210/WG1 to develop four ISO documents:

ISO 13485:1996 *Quality systems-Medical devices-Particular requirements for the application of ISO 9001*

ISO 13488:1996 *Quality systems-Medical devices-Particular requirements for the application of ISO 9002*

ISO 13485:2003 *Medical devices — Quality management systems — Requirements for regulatory purpose*

ISO/TR 14969:2004 *Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003*



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we've done so far...

Partnership with TC 210 controlled through a formal Memorandum of Understanding between GHTF and ISO

- GHTF SG3 given “Category A Liaison” status which means that SG3 members can participate in TC 210/WG1 meetings and provide working group experts
- Agree to avoid duplication of work
- Agree to work together
- Signed in 1999



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we've done so far...

Presently developing a new guidance document called *SG3N17 Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers*.

Existing regulatory requirements require organizations to control product and services obtained from suppliers (e.g. 4.1 & 7.4 of ISO13485:2003, Articles 5 and 37 - 39 of Japanese Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and in vitro Diagnostics (MHLW Ministerial Ordinance No. 169, 2004), and the FDA 1996 Quality System Regulation 21 CFR Part 820, paragraphs 50 and 80).

Regulatory requirements call for the type and extent of controls to be established and documented within the organization's quality management system.

Intent of SG3N17 is to provide harmonized guidance on type and extent of controls a manufacturer would use in the process of obtaining a product or service from a supplier



SG3

11th GHTF Conference
Washington DC, October 3-4, 2007

Barriers to implementation ...

General problems of implementing SG3 guidance into existing regulatory framework include.

- how, when, translation, legal status, etc...

SG3 documents should be easier to implement than other SG's as they provide "how to" guidance. Examples include integration of risk management (ISO 14971) into a quality management system (most commonly accepted QMS is ISO 13485:2003) or best practice on how to control suppliers and procured products.



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we plan to do in the near future...

Proposals for two new guidance documents have been submitted to the GHTF Steering committee for approval

One proposal deals with “Significance of QMS deficiencies” (is the deficiency global or local ? is it regulatory in nature?)

The other proposal deals with principles and activities related to regulatory “Corrective and Preventive Action” (CAPA) requirements imposed on medical device manufacturers as part of national or regional regulatory quality management systems. (intent is to harmonize understanding)



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we plan to do in the near future...

Start work on new work items soon (½ - 1 ½ yrs). Quality System deficiencies (SG3N19) will be given priority over the CAPA document (SG3N18)

Place “Proposed Document” version of SG3N17 (Supplier control) on GHTF website for international public comment (by end of 2007?)

1. review comments
2. revise “Proposed Document”
3. post as “Final” document (early/mid 2008)



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**

what we plan to do in the near future...

Participate in joint GHTF SG3 – ISO TC 210/WG1 meetings dedicated to topics like :

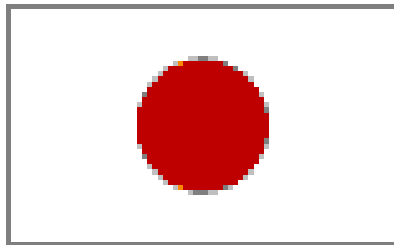
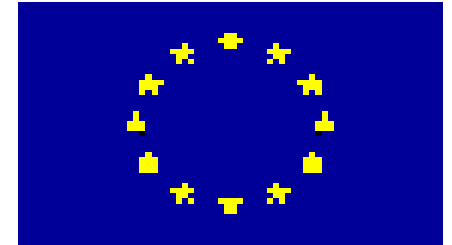
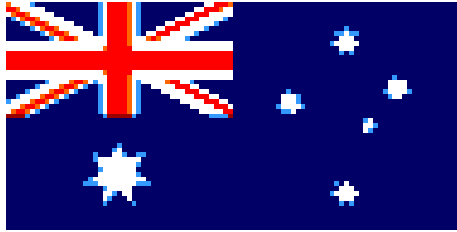
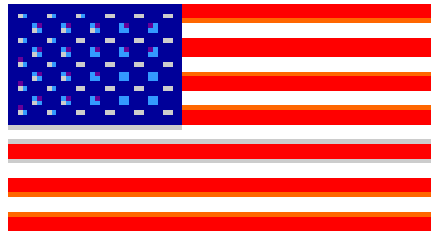
- review responses to ISO 13485:2003 and ISO/TR 14969:2004 global user survey
- conversion of ISO/TR 14969:2004 from an ISO “technical report” to an ISO “standard” or a GHTF guidance document
- significance of editorial and/or structural changes to ISO 9001:2000 and the impact of these changes on ISO 13485:2003

Participate in joint SG3-SG4 and ad hoc group meetings



SG3

**11th GHTF Conference
Washington DC, October 3-4, 2007**



Thank You ...