GHTF Study Group 3
Role, Members, Documents

4th APEC-Funded Seminar on
Harmonization of Medical Device Regulation
Kuala Lumpur
March 5-7, 2008

Gunter Frey
Vice Chair SG3

Role of Study Group 3

- "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.ghtf.org/sg3/sg3.htm

Members (2008)

Australia

- Mr Ken Nicol — MIAA/St. Jude
- Mr Keith Smith — TGA/MAB

Canada

- Mr Egan Cobbold — HC/MDB (Chair of SG3)
- Mr Jan Noupbaev — MEDEC/Medtronic Can.

European Union

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

Japan

- Mr Hideki Asai — JFMDA/Hitachi
- Mr Munehiro Nakamura — JFMDA/Kaneka
- Mr Shinichi Takae — MHLW

United States of America

- Ms Kimberly Trautman — FDA
- Mr Gunter Frey — NEMA/GE Healthcare (Vice-Chair/Sec of SG3)
- Mr Ken Kopesky — AdvaMed/Medtronic

SG3 Documents – the present

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 Documents – the future

Study Group 3 is currently working on a new guidance document that is intended to provide harmonized guidance for manufacturers on the control of products and services obtained from suppliers.

"SG3(WD)N17 Quality management system – Medical devices- Guidance on the control of products and services from suppliers". Expect to have a draft out for public comment by early 2008.

In next 4 to 5 years our plan is to develop 2 new guidance documents on "characterizing the significance of quality management system deficiencies", and "corrective and preventive action (CAPA) principles and activities."

SG3 Documents - partnership

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