



11th GHTF Conference

Study Group 4 – “Regulatory Auditing” Status Report

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Chair SG4

Washington DC

October 3-4, 2007



Overview on Report by SG4

Our Mission – the Vision of our Work

Membership

Document Status / Results Achieved

Present Working Items

New Working Items

Our Mission – the Vision of our Work

GHTF-Study Group 4 „Regulatory Auditing“

has been given the task to

- examine quality management system auditing practices
 - initially among the founding members of the GHTF
 - develop guidance documents laying down harmonized principles for the process of auditing manufacturers of medical devices
 - to promote effective auditing practices
- ... and thus contribute to the safety and effectiveness of medical devices for the benefit of all the stakeholders.

Our Mission – the Vision of our Work

GHTF-Study Group 4 „Regulatory Auditing“

has the vision that

in future times the results of one single audit of a medical device manufacturer will satisfy the needs of multiple regulatory schemes.

... To take away the burden of multiple auditing from the manufacturer, auditing organizations and regulators.

Confucius:

“He who will not economize will have to agonize.”

Membership

Representatives from

- Industry,
- Conformity Assessment Bodies and
- Regulators

	Industry	CABs	Regulators
USA	1		2
Canada	1		1
Japan	1		3
Australia			1
EU / EFTA / CH	3	2	2
Taiwan			1
Total:	6	2	10

Document Status / Results Achieved (1)

Main SG4 work under chairmanship of Robert Allen (1994 – 2001)

- SG4/N28 (99) Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
- **Supplements:**
 - Audit Language Requirements (1999)
 - Training Requirements for Auditors (2000)
 - Observed Audits of Conformity Assessment Bodies (2001)
 - Compilation of Audit Documentation (2002)

Document Status / Results Achieved (2)

Main SG4 work under chairmanship of Prof. Horst Frankenberger (2001 – 2006)

SG4/N30R20:2006

Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers
– Part 2: **Regulatory Auditing Strategy**

- process approach
- auditing of subsystems
- auditing of how risk management is implemented
- need to promote document and to train auditors!

Document Status / Results Achieved (3)

Main SG4 work under chairmanship of Prof. Horst Frankenberger (2001 – 2006)

- SD4 (PD)/N33
Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: **Regulatory Audit Reports**

Present Working Items (1)

- SG4/N28 (stage 4): **Part 1: General Requirements**
complete redesign to fit an entirely new environment of ISO/IEC standards (e.g. ISO 19011, ISO/IEC 17021)
- SG4(PD)/N33 (stage 5)
 - **Part 3: Regulatory Audit Reports**

How much harmonization is needed in order that reports are useful for various jurisdictions?

- content
- structure
- format



Present Working Items (2)

- SG4 N83: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers
 - Part 2: Regulatory Auditing Strategy, Supplement No. 1 Multi-site Audits and Audits of Suppliers
 - large manufacturing companies active on different sites
 - suppliers of critical components or services

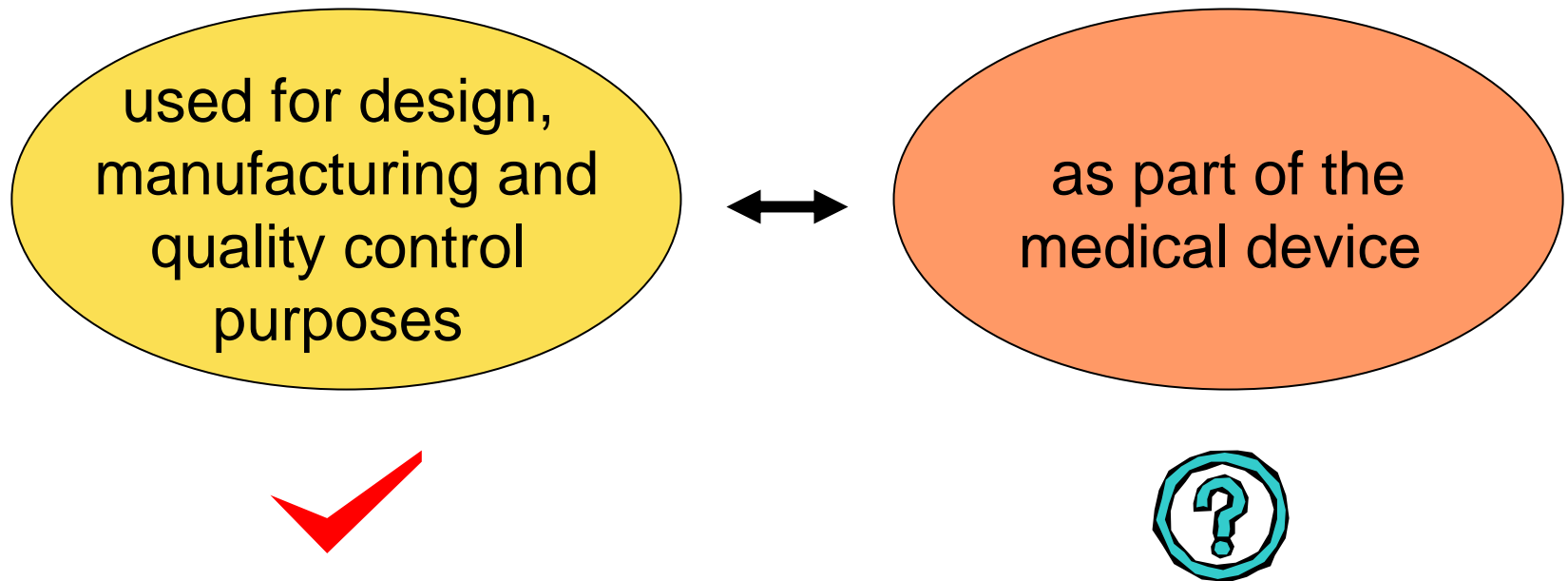


- “virtual manufacturers”

New Working Items

- Guidelines for “Auditing of Software”

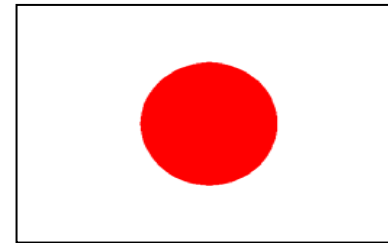
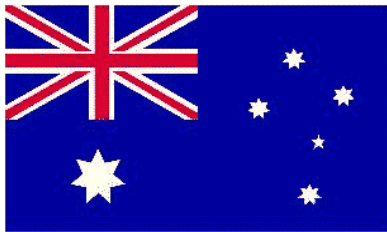
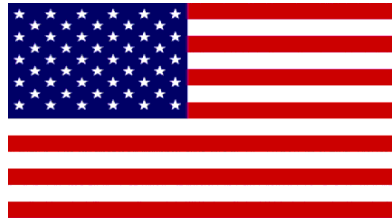
Software



New Working Items

SG4 process to develop guidance for auditing

1. clarify applicable standards/regulations for a QMS or a specific process (e.g. ISO 13485, ISO 14971, ISO 11137...)
2. clarify existing guidance for a manufacturer to implement a standard
(e.g. ISO 14969, SG3/N15R8/2005, SG3/N99-10...)
3. and then develop the requirements and techniques best suitable for auditing the item concerned



Thank You ...