GHTF/SG4/N30 R16:2005
(Final document 09/16/2005)

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

(- Part 1: General Requirements GHTF.SG4.(99)28)
History of GHTF/SG4/N30
(Regulatory Auditing Strategy)

• Sep. 2002 Start of Project in Lübeck
• Nov. 2003 Proposed document R6 submitted
• Sep. 2004 Final document R14 submitted,
• missing element: risk management
  (GHTF-SG3/15 R8: „Implementation of Risk Management Principles and Activities within a Quality Management System“)
• Sep. 2005 Integration of risk management process, joint session with SG3R16 Final Document
  2 days learning experience
Scope of document SG4/N30
Regulatory Auditing Strategy, Scope:
• Guidelines for auditing organisations,
• how to use process approach in conducting an audit
• for a Quality Management System (ISO 13485:2003)

ISO 13485:2003
20 pages of requirements
SG4/N30 R16 - Regulatory Auditing Strategy

Benefits for regulator + auditing organizations:

- improved auditing
- consistency
- promotes collaboration between regulators
- increased confidence in audits
- efficient use of resources
- guidance for countries establishing their own strategy for auditing
SG4/N30 R16 - Regulatory Auditing Strategy

Benefits for manufacturers:

• improved auditing (improve QMS, product)
• better consistency (valuable feedback for QMS)
• saving resources – easier to prepare audit
• increased confidence in audits and acceptance of audit results by different regulators
• reducing the number of times a single manufacturer is audited by different regulators
SG4/N30 - Regulatory Auditing Strategy (1)

ISO 13485:2003 uses Process Approach

Audit must be process oriented!

Quality Management System Processes

a) plan
b) do
c) check
d) act

No job is finished until the paperwork is done!
SG4/N30 - Regulatory Auditing Strategy (2)

Use of Subsystems: A logic for the auditing to cover all ISO 13485:2003 Quality Management System processes

Subsystems to cover Product Realization Process

- 7.2 Design and Development
- 7.3 Product Design Documentation
- 7.6 Purchasing Controls
- 7.4 Production and Process Controls

Subsystems covering the Supporting Processes

- 7.1 Management
- 7.5 CAPA
- 7.7 Documentation and Records
- 7.8 Customer Related Processes
SG4/N30 R16 - Regulatory Auditing Strategy

- Audit planning is included (as in previous Version)
- Audit duration is addressed: unchanged from previous version.
- Added: how to audit Risk Management requirements of ISO 13485:2003 (with SG3)
- Added clarification (scope and other parts)
Guidelines for Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

Scope:
Guidance for regulators and auditing organizations for writing reports of Quality Management System audits
GHTF/SG4/N33 R8
Part 3: Regulatory Audit Reports

Next step: elaborate proposed document
Nov. 14 - 16, 2005 in Lübeck
Future work

Revision of Part 1 documents to align to new Standards:

• ISO 13485:2003 and others

Give guidance for auditing special processes addressed by the QMS

• Software Validation and others
Thank you for your attention!