

GHTF Study Group 4 Regulatory Auditing

Overview of SG 4 Guidance Documents

Jan Welch

Secretary, GHTF-SG4

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GHTF Study Group 4

- ▶ Has been charged with the task of examining quality management system auditing practices (initially among the founding members of the GHTF) and developing guidance documents providing harmonized principles for the medical device auditing process



Study Group 4

- Provide guidance for parties responsible for establishing, planning, carrying out and documenting audits of quality systems to address regulatory requirements for manufacturers of medical devices
- Outline competence criteria for the auditing team
- Eliminate duplication of effort and inconsistencies in regulation across participating countries



Study Group 4

- Began work on the series of documents in 1994-1996
- At that time the ISO 10011 series of standards for auditing quality systems was available (1990-1991)
- Also available was ISO 14011:1996 for environmental auditing



SG 4 Guidance Documents

- Umbrella group of documents
- Guidelines for Regulatory Auditing Quality Management Systems of Medical Device Manufacturers
- Currently three parts



SG 4 Guidance Documents

- **Part 1: General Requirements**
- **Part 2: Regulatory Auditing Strategy**
- **Part 3: Regulatory Audit Reports**



Part 1

General Requirements

- Endorsed by GHTF in 1999
- Final document, current at this moment
- GHTF.SG4.(99)28
- <http://www.gh tf.org/sg4/inventor ysg4/99-28genreq.pdf>



Part 1

General Requirements

➤ Supplements added over time

- Supplement 1: Audit Language Requirements
GHTF.SG4.(99)14
- Supplement 3: Training Requirements for Auditors
GHTF.SG4.(00)3
- Supplement 4: Compilation of Audit Documentation
GHTF.SG4.N(99)24R3:2002
- Supplement 6: Observed Audits of Conformity Assessment
Bodies GHTF.SG4.N26R1:2001



Part 1

General Requirements

Includes guidance for:

- General principles for auditing organizations
- Audit objectives
- Audit scope
- Types of audits
- Roles and responsibilities of the various parties
- Audit team composition
- Audit process
- Corrective action followup



Part 1

General Requirements

- N 28 under revision at this time
- Proposed document with revisions sent to GHTF Steering Committee in late June 2007
- Should be posted this fall to GHTF website for six month comment period



Part 1

General Requirements

- Now in 2007 we have ISO 19011:2002 standard for quality and/or environmental systems auditing
- Also the ISO 17000:2004 and 17021: 20046 conformity assessment standards
- Needed to update the 1999 Part 1 GHTF document in light of current standards



Part 1

General Requirements

- Revised structure
- References to pertinent sections of relevant standards
- Elimination of duplicative information
- Updated with current terminology and practice



Part 1

General Requirements

- Proposed structure of revised N 28 document
 - General requirements of auditing organizations
 - Management
 - Resources
 - Audit process
 - Audit objectives and scope
 - Types of audits
 - Roles and responsibilities
 - Audit team composition
 - Audit team responsibilities
 - Documentation
 - Followup activities



Part 2

Regulatory Auditing Strategy

- SG4/N30R20:2006
- http://www.ghtf.org/sg4/inventorysg4/SG4N30R20-2006_auditing_strategy_FINAL.pdf
- Final as of August 31, 2006



Part 2

Regulatory Auditing Strategy

- Guidance to those conducting regulatory audits of medical quality management systems based on a process approach to QMS requirements
- Deals only with QMS regulatory requirements
- Audits are risk-based with a focus on the key processes of the QMS necessary to manufacture the medical devices covered by the audit



Part 2

Regulatory Auditing Strategy

- Structure of the guidance:
 - Objectives
 - Auditing Quality Management Systems (Subsystems)
 - Auditing Approaches
 - Process Based Auditing (PDCA cycle)
 - Sampling
 - Audit Planning (including audit time suggestions)
 - Guidance on Logistics
 - Subsystem Links
 - Details on Auditing the Subsystems



Part 2

Regulatory Auditing Strategy

➤ Section 7.0 Auditing Subsystems

- Risk management principles apply throughout the product realization process of a medical device and should be used to identify and address safety issues
- Risk management activities should be audited concurrently with the relevant subsystems
- Purpose of auditing the risk management process is to ensure that adequate and effective risk management has been established and maintained throughout the product realization process
- Can also assess the impact of the risk management process outputs on other areas of the QMS as mentioned in ISO TIR 14969



QMS Subsystems

- Management
- Design and development
- Product documentation
- Production and process controls
- Corrective and preventive actions
- Purchasing controls
- Documentation and records
- Customer related processes



Part 3

Regulatory Auditing Reports

- SG4(PD)N33R13:2006
- <http://www.ghtf.org/sg4/inventorysg4/SG4-PD-N33-R13-2006.pdf>
- Six month comment period from
December 15, 2006 – June 15, 2007



Part 3

Regulatory Auditing Reports

- Proposed document with revisions sent to GHTF Steering Committee in August 2007
- Recommended for a second comment period, shorter time of 60 days
- Hopefully will be posted on GHTF SG 4 web page in October 2007 for this shortened additional comment period



Part 3

Regulatory Auditing Reports

- The purposes of this document are to harmonize the content of audit reports and to provide guidance on best practices for reporting audit results
- This guideline promotes consistency in audit reports – important in harmonization and mutual acceptance of audit results
- This document may also be used in support of bilateral and multilateral agreements.



Part 3

Regulatory Auditing Reports

- This guideline will:
 - provide a structure for audit reports that may be used in multiple jurisdictions
 - promote consistency and uniformity and assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations
- Having reports that are consistent in content will facilitate the review and exchange of audit reports
- Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers



Part 3

Regulatory Auditing Reports

- Structure of document
 - Objectives and User Needs of a Regulatory Audit Report
 - Main Points of a Regulatory Audit Report
 - Data concerning auditee
 - Data concerning audit
 - Audit trail
 - Conclusion
 - Signature and dating of report
 - Attachments



Questions??

Jan Welch, MHS, MT(ASCP)SBB
Quality System/IVD Expert
Division of Enforcement A
HFZ-320

Office of Compliance
Center for Devices and Radiological Health
US Food and Drug Administration
2094 Gaither Road
Rockville, Maryland 20850 USA

Phone: (240) 276-0354

Fax: (240) 276-0114

Email: jan.welch@fda.hhs.gov

