Global Harmonization Task Force
Study Group 4 – Auditing

Asia-Pacific Economic Cooperation

GHTF

SG 4

Agenda

- Goals of SG 4 – Auditing
- SG 4 Membership
- Summary of guidance documents

GHTF SG 4 “Auditing” - Purpose

Purpose of Study Group SG4

- Guidance to Regulatory Audit Organizations, Auditors and Manufacturers of Medical Devices

„SG4 has been charged with the task of examining quality system auditing practices (initially among the founding members of the GHTF) and developing guidance documents laying harmonized principles for the medical device auditing process“

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Goals of GHTF SG 4

- Provide guidance for regulatory auditing of medical device manufacturers' quality systems
- Improve the effectiveness of regulatory audits
- Promote greater uniformity in the way regulatory bodies throughout the world conduct audits

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SG 4 Current Membership

- U.S. (3)
  - Regulatory (2)
  - Industry (1)
- Canada (2)
  - Regulatory (1)
  - Industry (1)
- Australia (1)
  - Regulatory (1)
- Europe (6)
  - Regulatory (1)
  - Industry (3 – **SG4 Chair & Secretary**)
  - EU Notified Bodies (2)
- Japan (4)
  - Regulatory (2)
  - Industry (2)

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SG 4 Final Guidance

SG4(99) 28

Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers

Part 1: General Requirements

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General Requirements

- Written for auditing organizations
- May also be useful for manufacturers
- Provides guidance for establishing, planning, carrying out and documenting regulatory audits of quality systems
- Describes competence criteria for the audit team

SG 4 Final Guidance

SG 4(99) 14

Part 1: General Requirements

Supplement 1

Audit Language Requirements

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Audit Language Requirements

- Purpose: To assure that auditors and the auditee are able to communicate clearly during an audit
- Before the audit, determine if auditors and auditee have a common language
- Arrange for an interpreter if there is no common language

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SG4(00) 3

Part 1: General Requirements

Supplement 2

Training Requirements for Auditors

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Training Requirements for Auditors

- The document describes training elements required to:
  - Prepare an individual to be an auditor
  - Qualify auditors to conduct regulatory audits of medical device manufacturers' quality systems
  - Maintain auditor qualifications

SG 4 Final Guidance

SG4 N(99) 24R3:

Part 1: General Requirements

Supplement No. 4

Compilation of Audit Documentation

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Compilation of Audit Documentation

- Provides guidelines for compiling audit documentation within auditing organization for internal use
- This document does not address the exchange of audit documentation between auditing organizations

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SG4-N26R1:2001

Part 1: General Requirements

Supplement No. 6

Observed Audits of Conformity Assessment Bodies

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Observed Audits of Conformity Assessment Bodies

- Sets out guidance for observing audits conducted by Conformity Assessment Bodies (CABs).
- Observing audits enables a regulatory authority to evaluate the adequacy of the CAB's audits

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SG 4 Proposed Guidance

SG4/N30R6

Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers

Part 2:

Regulatory Auditing Strategy

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Regulatory Auditing Strategy

- Provides guidance on how to audit the effectiveness of quality systems in a systematic and effective manner within a reasonable time
- Purpose is to promote audit consistency – a necessity for harmonization and mutual recognition of audit results.

SG 4 Documents Under Development

SG4/N33:

Part 3

Audit Reports

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Audit Reports

- Will provide harmonized content for reporting results of regulatory audits of quality systems
- Purpose is to facilitate the exchange of regulatory audit reports among regulatory authorities

SG 4 Documents Under Development

SG4/N30 R 13:

Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers

Part 2:

Regulatory Auditing Strategy

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Regulatory Auditing Strategy

- Will be revised to provide guidance for regulatory auditing of risk management activities within the quality system

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