



Study Group 4

Status of the Group's work, current standing, future directions

Markus Zobrist, Swissmedic -
Swiss Agency for Therapeutic Products

Study Group 4



Mission

People

Professor Horst Frankenberger
(Interim Chair, absent)

Contributing to this meeting:

Australia – Government

China – Government

Canada – Industry

Europe - Industry

Europe – Notified Bodies

Japan - Government

Japan – Industry

Taiwan - Government

U.S.A. – Government

U.S.A. – Industry

Mr. Andrew Muir

Mr. Chen Zhigang / Ms. Zhang Mingzhu

Mr. Tim Missios

Mr. Dierk Bellwinkel, (Secretary)

Mr. Johann Rader

Ms. Makiko Isozaki

Mr. Kenji Aoyama + Mr. Morichika Tanemura

Mr. Albert T.W. Li

Ms. Karen Coleman+ Ms. Christine Nelson

Mr. Robert L. Turocy

+ Singapore **Government** + **Industry** + many more observers!!!

Revision of Document SG4(99)24 as Rev3 for approval



”Supplement 4, Compilation of Audit Documentation”

Industries’ concerns to be removed:

- insufficient rationale for purpose
- unclear on use of the compiled audit documentation
- potential for misinterpretation - transfer of documents

Revision of Document SG4(99)24 as Rev3 for approval



”Supplement 4, Compilation of Audit Documentation”

Action by SG4: amend the document

1. Explaining the benefits for compiling audit documentation for:
 - auditing organisation
 - manufacturer

Revision of Document SG4(99)24 as Rev3 for approval



”Supplement 4, Compilation of Audit Documentation”

Action by SG4:

2. Addition of the scope:

- compiling audit documentation within auditing organisation **for internal use**
- **addresses not** exchange of audit documentation between organisations

Revision of Document SG4(99)24 as Rev3 for approval



”Supplement 4, Compilation of Audit Documentation”

Action supported and approved by:

1. Industry representatives in SG4 (Consensus with industry: Canada, Europe, Japan, U.S.A.)
2. GHTF Steering Committee (Monday 13.05.02)

**SG4(99)24
be published**



www.ghtf.org

Study Group 4

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Objectives of this guideline

- tool for auditing such that one audit satisfies the needs of multiple jurisdiction
- covering all elements of QS Standard ISO 13485:200X

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Objectives (cont.)

- assures audit coverage of regulatory requirements (AU U.S.A.)
- incorporate principles of SG4(99)10
“Estimation of Audit Duration”

Quality System Audit Strategy for Regulatory Purposes



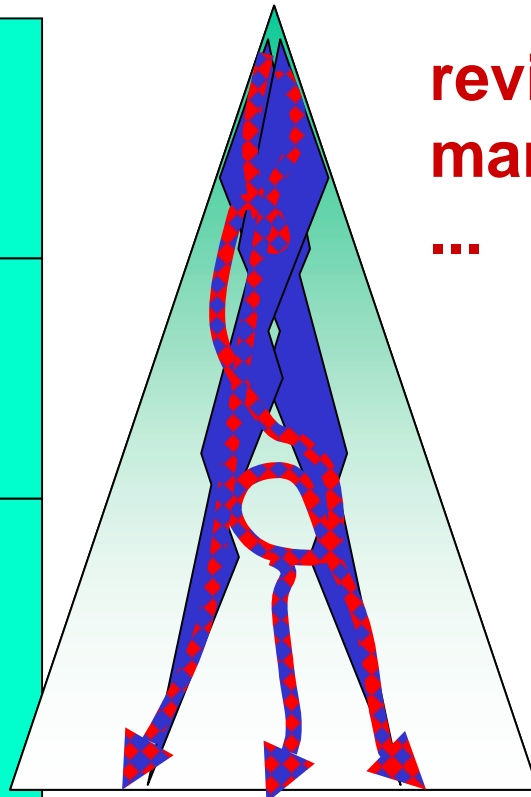
New work item started in SG4

Audit objectives

completeness
suitability
of the QS + RR

suitability of
procedures /
processes

effective
application
of procedures
processes



Audit activities

review quality manual,
management responsibility

...

check processes,
validations ...

sample:
Q-data,
products ...

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

References available?

- FDA's "Quality System Inspection Technique" (QSIT)
- no other guidance document available!



use QSIT as a reference!

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Benefits for auditing organisation + Regs.

- improved quality of audits
- improved consistency in audits within and between auditing organisations (AO)
- enhances collaboration between AO/Regs.
- increase quality of, confidence in, acceptance of audit results by other AO/Regulators

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Benefits for auditing organisation + Regs.

- saving resources
- improved quality of audit -> improvement of QS and product
- improves auditor training
- guidance for new emerging countries

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Benefits for manufacturer

- improved quality of audit -> improvement of QS and product
- saves resources by reducing number of audits
- increases consistency in audits
- one approach - easier preparation for audit

Quality System Audit Strategy for Regulatory Purposes



New work item started in SG4

Work done this meeting:

- Project plan finalized
- two meeting dates until May 2003
- project elements defined and distributed to SG4 members to draft until Sept. 2002

Ambitious project plan:

to have a document for circulation in May 2003



Activities scheduled - Proposed merger with SG3:

- SG4 work items have to be finished
- need for a reconsideration of the merging date?