

GHTF-SG4 „Regulatory Auditing“

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Chair GHTF-SG4

Luebeck, June 2006

GHTF-Study Group 4 „Regulatory Auditing“

has been charged with the task of

- examining quality system auditing practices - initially among the founding members of the GHTF
- developing guidance documents laying harmonized principles for the medical device auditing process

GHTF-Study Group 4 „Regulatory Auditing“

1st meeting: June 1994

Chair Robert Allen – Europe – Regulator
1994 – 2001

Horst Frankenberger – Europe – Industry: EUROM VI
2002 – June 2006

Dierk Bellwinkel – Europe – Industry: EUROM VI, FIDE
Secretary

Markus Zobrist – Europe-EFTA – Regulator: SWISSMEDIC
July 2006

Jane Welch – USA – Regulator: FDA
Secretary

Membership Structure of GHTF-SG4

| | Industry | Notified Body | Regulator |
|-----------|----------|---------------|----------------|
| Europe | 3 | 2 | 1 ^a |
| USA | 1 | | 2 |
| Canada | 1 | | 1 |
| Japan | 2 | | 2 |
| Australia | - | | 1 |
| Taiwan | - | | 1 |
| | 7 | 2 | 8 |

^a : 1 place empty – to be replaced by EU-Commission

GHTF-Study Group 4 „Regulatory Auditing“

has developed / is developing a set of guidance documents dealing with

Guidelines for Regulatory Auditing Quality Management Systems of Medical Device Manufacturers

- **Part 1: General Requirements (Final)**
- **Part 2: Regulatory Auditing Strategy (Final)**
- **Part 3: Regulatory Audit Reports (Proposed Document to be sent to GHTF-SC after Luebeck conference)**

GHTF-Study Group 4 „Regulatory Auditing“

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

Part 1: General Requirements

Final - since 1999

Revision started at GHTF-SG4 meeting in
June 2006

Contents

1. Introduction
2. Scope
3. References
4. Definitions
5. General principles for auditing organizations
6. Audit objectives
7. Audit scope
8. Types of audit
9. Roles and responsibilities
10. Audit team
11. Audit process
12. Corrective action follow-up

6. Audit objectives

Audits are designed to

- a. determine conformance of a manufacturer's quality system with regulatory requirements
- b. determine the effectiveness of the implemented quality system for the purposes of meeting the specified quality objectives which include all of the appropriate medical device regulatory requirements
- c. audit the quality system as the manufacturer has defined it
- d. In the case of audits subsequent to the initial audit, ensure that corrective actions agreed as a result of the previous audit have been completed effectively

8. Types of audit

1. Initial audit

2. Surveillance audit

3. Special audit – e.g.:

- Available post-market data on the subject devices indicate a possible significant deficiency in the quality system
- Significant safety related information becoming known to the auditing organization
- Significant changes occur to the manufacturer which could affect the decision on the manufacturer's state of compliance with the regulatory requirements

4. Unannounced audit

- Justifiable concerns about implementation of CAPA or compliance with regulatory requirements

Supplements

Supplement 1: Audit Language Requirements

Supplement 3: Training Requirements for Auditors

Supplement 4: Compilation of Audit Documentation

Supplement 6: Observed Audits of Conformity
Assessment Bodies

GHTF-Study Group 4 „Regulatory Auditing

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

Part 2: Regulatory Auditing Strategy

SG4/N30R20

Final - since June 2006

Contents

1. Introduction
2. Scope
3. Rationale
4. References
5. Definitions
6. General remarks on regulatory auditing strategy
 - 6.1 Objectives
 - 6.2 Auditing quality management systems
 - 6.3 Auditing approaches
 - 6.4 Process based auditing
 - 6.5 Sampling
 - 6.6 Audit planning
 - 6.7 Guidance for logistics during an audit
 - 6.8 Links

Contents

- 7. Auditing subsystems
 - 7.1 Management subsystem
 - 7.2 Design and development subsystem
 - 7.3 Product documentation subsystem
 - 7.4 Production and process controls subsystem
 - 7.5 CAPA Subsystem
 - 7.6 Purchasing controls subsystem
 - 7.7 Documentation and records subsystem
 - 7.8 Customer related processes subsystem

Contents

Appendices

Appendix 1: Binomial staged sampling plans

Appendix 2: Factors used to determine audit duration

Appendix 3: Cross reference between ISO 13485 and 21 CFR Part 820

SG4/N30R20 - Regulatory Auditing Strategy

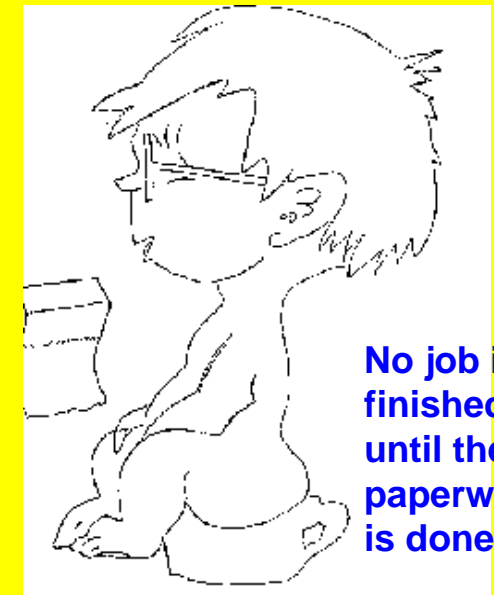
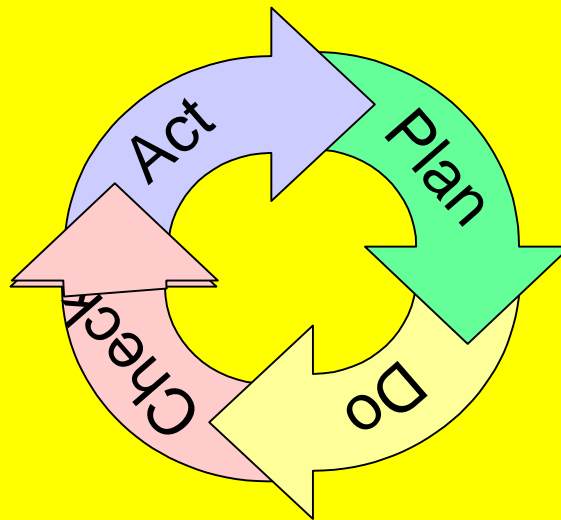
ISO 13485:2003 uses Process Approach

→ Audit has to be process oriented!

Quality Management System Processes

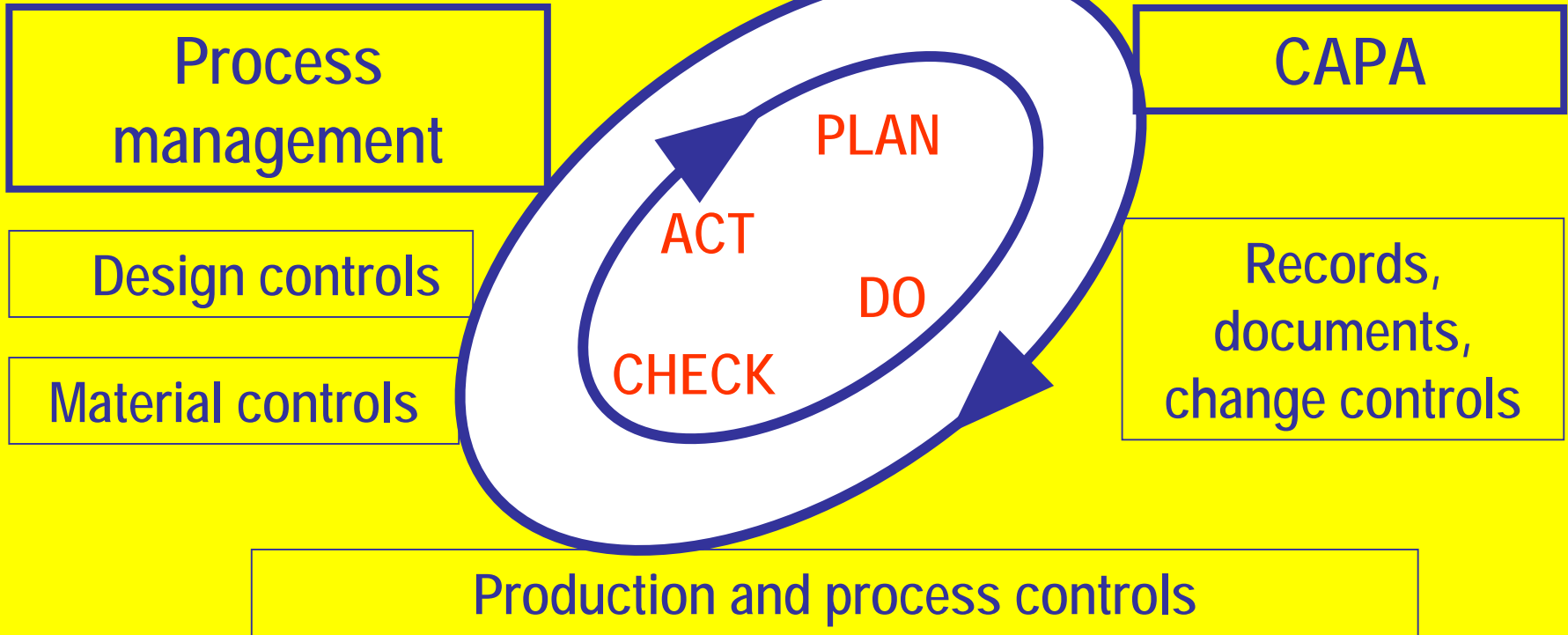
Quality Management System Processes

- a) Plan
- b) Do
- c) Check
- d) Act



Regulatory Audit of the Quality Management System

Start - Management controls - Stop



GHTF-Study Group 4 „Regulatory Auditing

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

Part 3: Regulatory Audit Report SG4/N33R13

Will be presented to the GHTF-SC after the
Luebeck Conference as proposed document

Contents

1. Introduction
2. Scope
3. Purpose
4. Rationale
5. References
6. Definitions
7. Objectives and user needs of a regulatory audit report
 - 7.1 Audit report objectives
 - 7.2 User needs for the auditing organization / regulatory authority
 - 7.3 User needs for the designating authority that observes the auditing organizations
 - 7.4 User needs for the manufacturer / auditee

Contents

8. Main points of an audit report

8.1 Data concerning auditee

8.2 Data concerning audit

8.3 Audit trail

8.4 Conclusion

8.5 Signature and dating of report

8.6 Attachments

Audit plan(s) – if applicable

Attendance sheet for opening and closing meetings

Relevant auditing organization documents

Evidence available to support the nonconformities

Checklist used by the auditor

Nonconformities identified at audit (if not included in the main body)



GHTF-SG4-Training Seminars

after GHTF-SG4 meetings in

| | |
|---------|-----------------------------|
| Luebeck | March 1999 |
| Luebeck | September 2002 |
| Berne | September 2003 |
| Tokyo | May 2004 |
| Sydney | September 2004 |
| Taipei | February 2006 |
| Luebeck | June 2006 – GHTF Conference |



**Thank you very much for
your attention**



**All the best for the future of the
GHTF**

**Horst Frankenberger
Chair GHTF-SG4 „Regulatory Auditing“**

