GHTF-SG4 „Regulatory Auditing“
1994 – 2006

Prof. Dr. Horst Frankenberger
Chair GHTF-SG4

Luebeck, June 28, 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) and developing guidance documents laying harmonized principles for the medical device auditing process
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)
GHTF-Study Group 4 „Regulatory Auditing“
- started in June 1994
- has today 16 members
  - 7 regulators
  - 2 notified bodies
  - 7 industry representatives
Phase 1994 – 2001

- First meeting June 13 – 14, 1994 in Montreal

  Chair: Robert Allen – Europe – Regulator

  Don Boyer  
  Don Serra  
  Carolyn Woodruff  
  Kenji Aoyama  
  Masato Yoshida  
  Egid Hilz  
  Erich Courtin  
  Horst Frankenberger  
  David Marshall  
  Johann Rader  
  Jacob Nordan

  Canada – Regulator  
  USA – Regulator  
  Australia – Regulator  
  Japan – Industry  
  Japan – Industry  
  Europe – Industry  
  Europe – Industry  
  Europe – Industry  
  Europe – Notified Body  
  Europe – Notified Body  
  Europe – EFTA – Regulator
**Phase 1994 – 2001**

### Meetings:

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<td>Tokyo</td>
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<td>Vancouver</td>
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<td>March 8 – 19, 1999</td>
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Phase 1994 – 2001

- Meetings:
  - Washington June 27 – 30, 1999 GHTF Conference
  - Dublin October 13 – 15, 1999
  - Munich March 15 – 17, 2000
  - Montreal June 5 – 6, 2000
  - Ottawa September 18 – 20, 2000 GHTF Conference
  - London February 28 – March 1st, 2001
  - Singapore May 12 – 14, 2002 GHTF Conference
Phase 1994 – 2001

- New members:
  Penny Ellwood, Canada - Regulator
  Christine Nelson, USA - Regulator
  Karen Coleman, USA - Regulator
  Robert Wurzel, USA - Industry
  Markus Zobrist, Europe-EFTA - Regulator
  Andrew Muir, Australia - Regulator
  Egan Cobold, Canada - Regulator
  Tsutomu Urano, Japan – Regulator
  Tanemura Morichika, Japan - Industry
  Ingeborg Hagerup-Jensen, Norway-EFTA - Regulator
  Albert Li, Taiwan - Regulator
  Tim Missios, Canada - Industry
  Anne-Marie Coutu, Canada - Regulator
  ...

GHTF-SG4
Phase 1994 – 2001

- First guidance document: Guidelines for regulatory auditing quality systems of medical device manufacturers – Rev. 4 – 1996

- Testing of the guidance document via “Observed Audits“ for feedback to the guidance document

- First presentation of GHTF-SG4 activities at the GHTF-Vancouver Conference in June 1995
Phase 1994 – 2001
Guidelines for regulatory auditing quality systems of medical device manufacturers

- 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

Aim
Eliminate duplication of effort and inconsistencies in regulation across participating countries
Phase 1994 – 2001
Guidelines for Regulatory Auditing Quality Systems of Medical Device Manufacturers
Part 1: General Requirements
  ● endorsed by GHTF in June 1999
    Final Document GHTF.SG4.(99)28

  ● Supplements to Part 1 were finalized
    - Supplement 1: Audit Language Requirements GHTF.SG4.(99)14
    - Supplement 3: Training Requirements for Auditors GHTF.SG4.(00)3
Phase 1994 – 2001

- Total number of meetings in this phase: 17
- High acceptance and transposition of the Part 1 document
- Highlights
  - Consensus oriented meetings
  - Observed audits as feedback information for guidance documents
  - First GHTF-SG4 training seminar in Luebeck
Phase 2002 – 2006

- GHTF Steering Committee nominated Horst Frankenberger as interim chair of GHTF-SG4 in May 2001 – after retirement of Robert Allen – in June 2004 as chair
- Dierk Bellwinkel acts as industry member of SG4 and secretary since 2001
- Markus Zobrist is elected as vice chair in 2005 and chair in June 2006
- New members:
  - Robert Turocy, USA - Industry
  - Jan Welch, USA – Regulator – secretary starting July 2006
  - John Worroll, Europe - Notified Body
  - Yamamoto Junji, Japan - Regulator
  - Imai Maki, Japan – Regulator
  - Miura Shigetaka, Japan - Industry
  - Philippe Lartigue, Europe – Industry
  - Reiner Krumme, Europe – Notified Body
  - Bertram Koenig, Europe - Industry
Phase 2002 – 2006

Meetings:

- Singapore: May 12 – 14, 2002, GHTF Conference
- Luebeck: September 16 – 17, 2002, SG4-Training Seminar
- Rockville: February 10 – 12, 2003
- Berne: September 22 – 24, 2003, SG4-Training Seminar
- Atlanta: February 19 – 21, 2004
- Tokyo: May 19 – 21, 2004, SG4-Training Seminar
- Canberra: September 27 – 30, 2004, SG4-Training Seminar
- Natick/Boston: April 4 – 7, 2005
- Gaithersburg: September 12 – 16, 2005
- Luebeck: November 14 – 16, 2005
- Taipei: February 14 – 16, 2006, SG4-Training Seminar
- Luebeck: June 25 – 30, 2006, GHTF Conference
Phase 2001 – 2006

- **Structure of GHTF-SG4 guidance documents**
  - Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - **Part 1: General Requirements**
    Status: Final Document

  - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - **Part 2: Regulatory Auditing Strategy**
    Status: Final Document

  - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - **Part 3: Regulatory Audit Report**
    Status: Proposed Document
ISO 13485:2003 uses Process Approach
→ Audit has to be process oriented!

Quality **Management System Processes**

A system consists of subsystems:

- Management
- Design and development
- Product documentation
- Production and process controls
- CAPA
- Purchasing
- Documentation and records
ISO 13485:2003 uses Process Approach

Audit has to be process oriented!

Quality Management System Processes

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

No job is finished until the paperwork is done!
Regulatory Audit of the Quality Management System

Start - Management controls - Stop

Process management

Design controls

Material controls

Production and process controls

CAPA

Records, documents, change controls

PLAN

ACT

DO

CHECK
Proposal to the GHTF-Steering Committee

Focus of GHTF-activities and the 10th GHTF Conference: „Design for patient safety in a global regulatory model“

The global regulatory model is developed by the GHTF-Study Groups under the supervision of the GHTF-Steering Committee, but there is no agreed specification of the global regulatory model
Proposals to the GHTF-Steering Committee
Focusing on the management principle:

There should be a plan - the specification - of the global regulatory model – a plan worked out by all SG-chairs and members of SC.
Proposals to the GHTF-Steering Committee

Rationale:
Today each SG prepares a workplan by his own – without referring how the workplan relates to the specification of the global regulatory model.

This specification should allow to point out the areas to be treated. Discussions if a SG should be active, dormant or merged can be decided more easily and objectively.
Thank you very much for your active cooperation.

All the best for the future of GHTF-SG4 „Regulatory Auditing“
Horst Frankenberger + Dierk Bellwinkel