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	Canada – Regulator
Don Serra	USA – Regulator
Carolyn Woodruff	Australia – Regulator
Kenji Aoyama	Japan – Industry
Masato Yoshida	Japan – Industry
Egid Hilz	Europe – Industry
Erich Courtin	Europe – Industry
Horst Frankenberger	Europe – Industry
David Marshall	Europe – Notified Body
Johann Rader	Europe – Notified Body
Jacob Nordan	Europe – EFTA – Regulator

Phase 1994 – 2001

- Meetings:

Brussels	September 22 – 23, 1994	
Tokyo	January 26 – 27, 1994	
Vancouver	June 1995	6th GHTF Conference
Brussels	October 18 – 19, 1995	
London	September 26 – 27, 1996	
Canberra	March 17 – 18, 1997	
Munich	September 25 – 26, 1997	
Sydney	February 19 – 21, 1998	
Toronto	June 8 – 10, 1998	
London	November 9 – 11, 1998	
Luebeck	March 8 – 19, 1999	SG4-Training Seminar

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
...

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
  - Supplement 4: Compilation of Audit Documentation GHTF.SG4.N(99)24R3:2002
  - Supplement 6: Observed Audits of Conformity Assessment Bodies GHTF.SG4.N26R1:2001

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

SG4/N30 - Regulatory Auditing Strategy

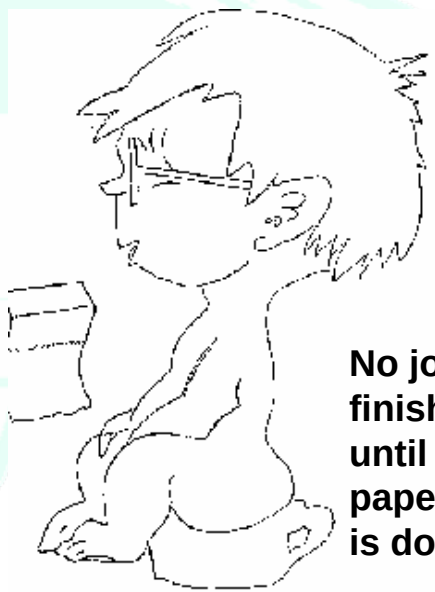
ISO 13485:2003 uses Process Approach

→ 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



No job is finished until the paperwork is done!

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SG4/N30 - Regulatory Auditing Strategy

ISO 13485:2003 uses Process Approach

→ Audit has to be process oriented!

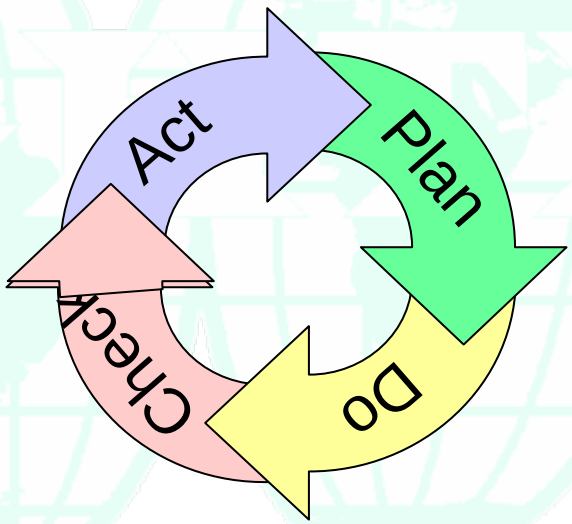
Quality Management System Processes

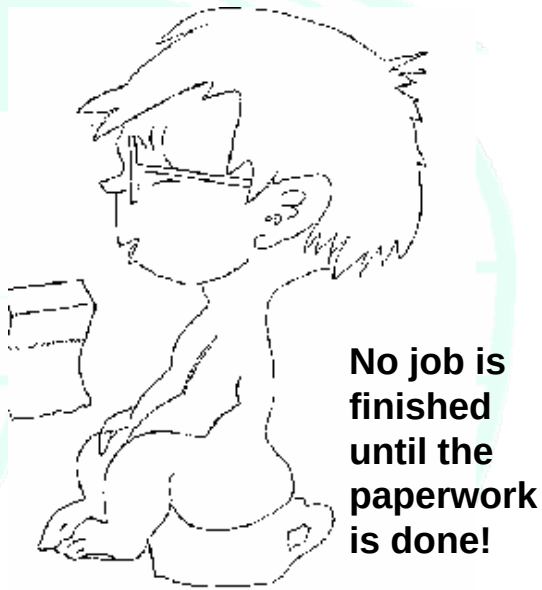
a) Plan

b) Do

c) Check

d) Act





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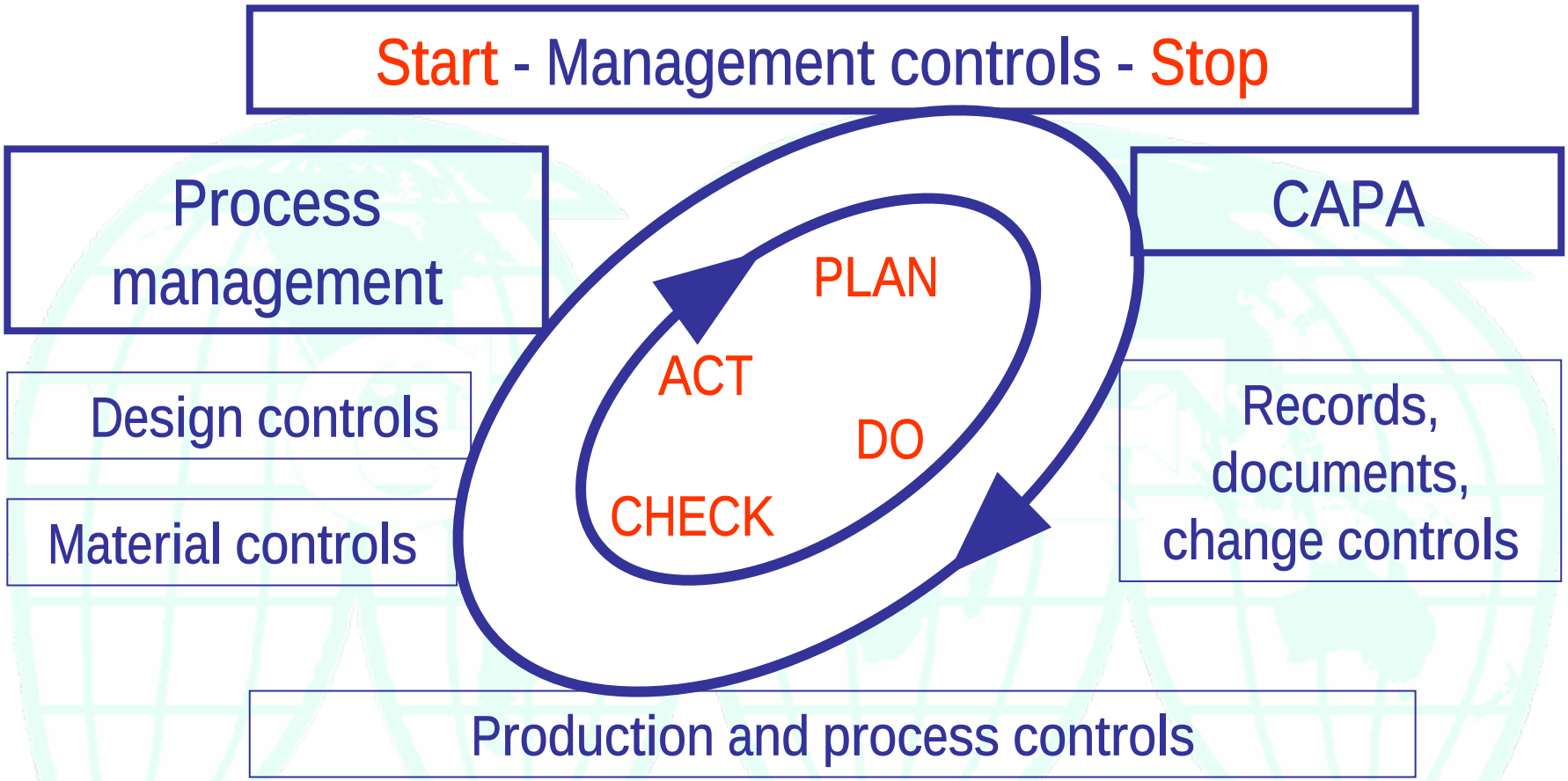
Regulatory Audit of the Quality Management System



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 prepars 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

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