GHTF SG4 Auditing

Gaithersburg Meeting September 12 – 15

(Chair SG4: Prof. Horst Frankenberger)

Acting chair this meeting: Markus Zobrist, PhD, Inspector

swissmedic

Swiss Agency for Therapeutic Products, Berne, Switzerland

GHTF/SG4/N30 R16:2005
(Final document 09/16/2005)

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

Part 2: Regulatory Auditing Strategy

(- Part 1: General Requirements GHTF.SG4.(99)28)

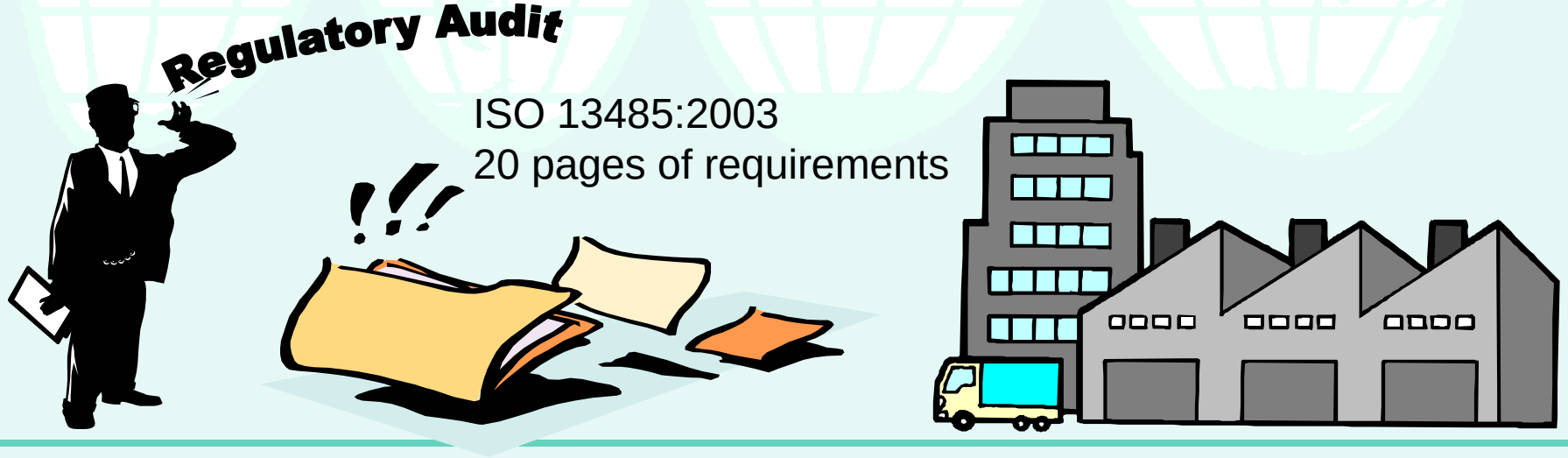
History of GHTF/SG4/N30
(Regulatory Auditing Strategy)

- Sep. 2002 Start of Project in Lübeck
- Nov. 2003 Proposed document R6 submitted
- Sep. 2004 Final document R14 submitted,
- missing element: risk management (GHTF-SG3/15 R8: „Implementation of Risk Management Principles and Activities within a Quality Managament System“)
- Sep. 2005 Integration of risk management process, joint session with SG3R16 Final Document
  → 2 days learning experience

Scope of document SG4/N30

Regulatory Auditing Strategy, Scope:

- Guidelines for auditing organisations,
- how to use process approach in conducting an audit
- for a Quality Management System (ISO 13485:2003)



SG4/N30 R16 - Regulatory Auditing Strategy

Benefits for regulator + auditing organizations:

- improved auditing
- consistency
- promotes collaboration between regulators
- increased confidence in audits
- efficient use of resources
- guidance for countries establishing their own strategy for auditing

SG4/N30 R16 - Regulatory Auditing Strategy

Benefits for manufacturers:

- improved auditing (improve QMS, product)
- better consistency (valuable feedback for QMS)
- saving resources – easier to prepare audit
- increased confidence in audits and acceptance of audit results by different regulators
- reducing the number of times a single manufacturer is audited by different regulators

SG4/N30 - Regulatory Auditing Strategy (1)

ISO 13485:2003 uses Process Approach

→ Audit must be process oriented!

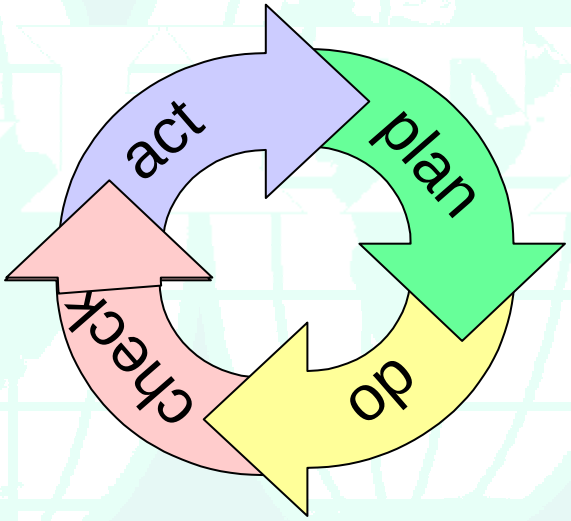
Quality Management System Processes

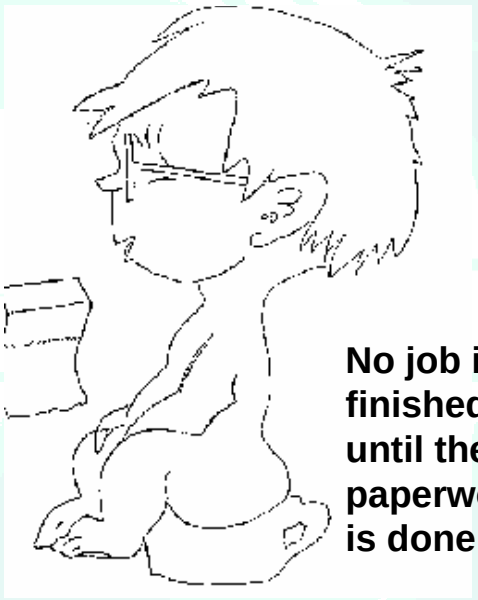
a) plan

b) do

c) check

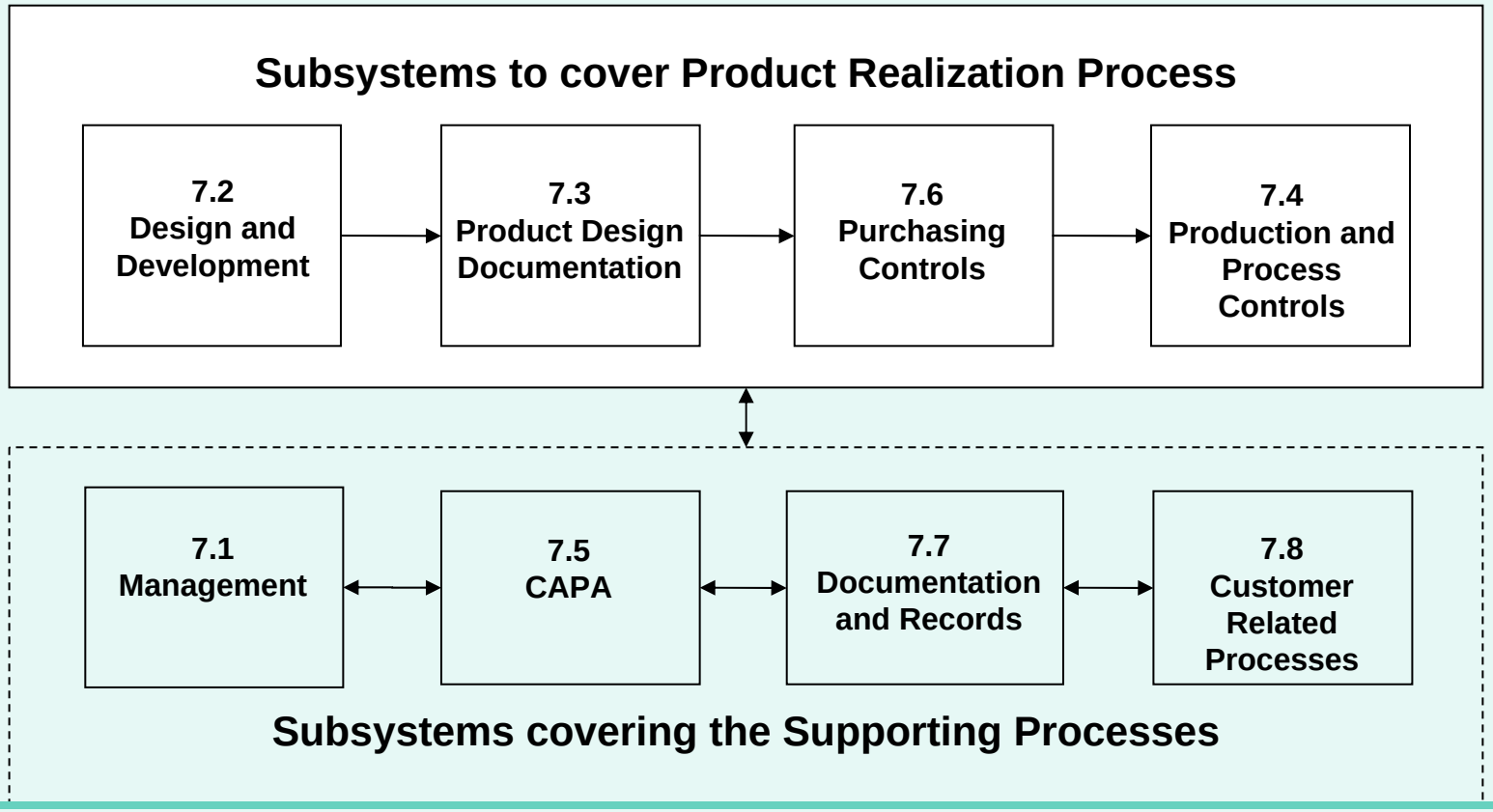
d) act





SG4/N30 - Regulatory Auditing Strategy (2)

Use of Subsystems: A logic for the auditing to cover all ISO 13485:2003 Quality Management System processes



SG4/N30 R16 - Regulatory Auditing Strategy

- Audit planning is included (as in previous Version)
- Audit duration is addressed: unchanged from previous version.
- Added: how to audit Risk Management requirements of ISO 13485:2003 (with SG3)
- Added clarification (scope and other parts)

GHTF/SG4/N33 R8
(Working Draft)

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

Part 3: Regulatory Audit Reports

Scope:
Guidance for regulators and auditing organizations for writing reports of Qualitity Management System audits

GHTF/SG4/N33 R8
Part 3: Regulatory Audit Reports

Next step: elaborate proposed document
Nov. 14 - 16, 2005 in Lübeck

Future work

Revision of Part 1 documents to align to new Standards:

- **ISO 13485:2003 and others**

Give guidance for auditing special processes addressed by the QMS

- **Software Validation and others**

Thank you for your attention!