

Audit Approaches

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Auditing of Quality System

Audit

“Systematic, independent + documented process for obtaining evidence and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled.”

ISO 9000:2000, Pt. 2.9.1

Audit criteria

“Set of policies, procedures or **requirements** against which collected audit evidence is compared.”

ISO 9000:2000, Pt. 2.9.4

Requirement

“Need or expectation that is stated, customarily implied or obligatory.”

ISO 9000:2000, Pt. 2.1.2

Obligatory needs for Medical Devices: Regulatory Requirements

Quality System Standards and/or Regulatory Codes

- ISO 13485, EN 46001
- ISO 9001
- GMP (e.g. US CFR 820 ff)
- other Regulatory Codes (e.g. EU Directives)

Auditing

the manufacturers quality system:

- to plan
- to collect objective evidence
- to evaluate
- to document ...

in order to determine the extent of the manufacturers compliance with the requirements of standards and of medical device regulations.

Auditing

who does the job:

- a single auditor,
- an auditor team,
 - being qualified + trained + competent
 - impartial
 - independent of the auditee/his products
 - conflict of interests must be excluded!
 - confidentiality
 - code of ethics

Auditing

auditor/auditor team:

- being part of an **auditing body**

auditing body:

- operating according to regulatory requirements for quality system

Auditing

Standards:

ISO 11001:1990

„Guidelines for auditing quality systems“

Part 1: Auditing

Part 2: Qualification criteria for quality systems auditors

Part 3: Management of audit programs

(will soon be replaced, ISO/DIS 19011:2001)

Approaches to Audit

Europe, Canada, Australia + ...

Procedures of Notified Bodies, Registrars
Conformity Assessment Bodies (CABs)

- top down approach (risk oriented),
- can follow the logic of the QS standard or
- QS + Process description of the manufacturer
- regulatory requirements for QS: included
- regulatory requirements for products

Approaches to Audit (Europe...)

Objective

**completeness
suitability
of the QS
suitability of
procedures /
processes
effective
application
of procedures
processes**

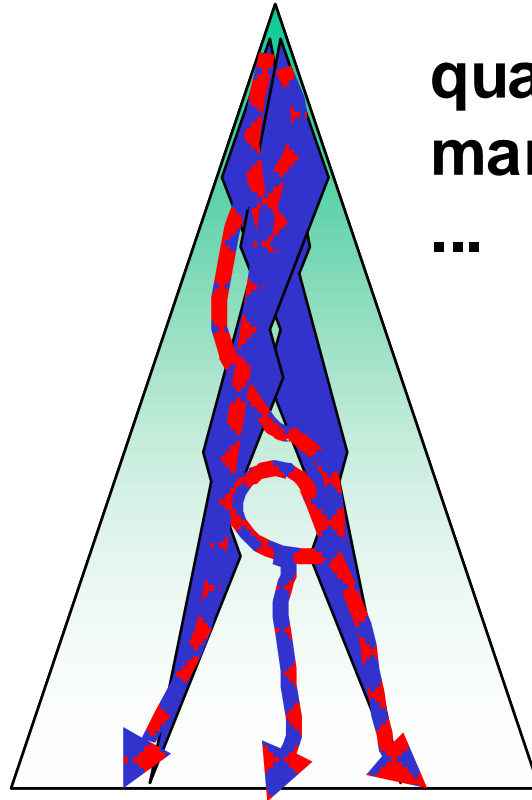
Audit activity

**quality manual review,
management responsibility**

...

**check processes,
validations ...**

**sample:
Q-data,
products ...**



Approaches to Audit, common

Depth of audit

- elements as in the audit scope with respect to the *regulatory requirements*
- sample documents and **records at all levels**

The samples chosen should **reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range of devices produced and any available post market surveillance data.**