

# **CRITICAL REVIEW OF THE DRAFT GUIDELINE**

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## General comments

- The purpose of this guideline has been clearly described
- All key issues are presented regarding in auditing
- Clear main structure
- Comparison with other quality assessment systems and regulatory inspections is helpful
- Starting from aims and objectives is a good way to start
- *But some changes are needed*

## Clearness of the guideline

- Audit
- Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled (ISO 17000)
- **Audit of system not individual employees/professionals**
- Internal/external audits, the difference
- Partial audit/comprehensive audit
- Quality management system, quality indicators
- Use of good practice criteria

## **Roles and responsibilities in clinical audits**

- Planning, audit operation, using the results
- The management of the institute/organisation
- The external audit organisation, competence
- Auditors
- Confidentiality/reporting to authorities

## Comments for the use of the guideline

- The guideline should be shorter, easier to understand and use
- The order of some items should be changed to clarify the guideline
- Some quite specific recommendations
- Good practice part of the guideline is partly written to the organisation and partly to the auditors
- The biggest cost is to build a quality management system and maintain it

## Relation of clinical audit with other quality assessment activities

- Accreditation
- Assessment of **competence**, based on international laboratory standards, special standard for medical laboratories (ISO 15189)
- Quality management system and patient examinations
- Certification
- The issue of a statement by third-party that **fulfilment** of specific requirements has been demonstrated (ISO 9001)