

Audits and Inspections

The EU Directive requires that each member country has its own inspection programme with its own inspectors.

ICH GCP guidelines require that Sponsors/CROs have their own quality system with audit programmes. Thus, audits and inspections are an integrated part of work with clinical trials.

The aim of this training course is to provide participants with an increased understanding of what it means to be audited and inspected. Furthermore, the course will provide an increased understanding of what can be done to prepare for an audit or inspection and how one should respond to an audit report.

Description

- What is an audit?
- What is an inspection?
- Regulations
- Preparing for an audit/inspection
- Following up an audit/inspection
- Normal findings during audits and inspections

Target group

Clinical Research Professionals who want a better understanding of audits/inspections. Recommended for Clinical Research Associates and Project Leaders.

Course leader

- Alistair Bone, Director of Quality Assurance and Training

Cost

The cost for the course is EURO 375 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 400 + VAT. The price includes morning and afternoon coffee as well as lunch.

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