

## Good Clinical Practice - basic

The aim of this course is to provide a practical introduction to GCP as described in the ICH E6 guideline and EU Directives.

Participants will learn about the ethical issues, requirements for subject safety and the roles and responsibilities of those working in clinical research.

### Description

- History of GCP
- Declaration of Helsinki
- Principles of GCP
- Ethics Committee
- Investigator's responsibilities
- Sponsor's responsibilities
- Safety reporting (AE, SAE, SUSAR)
- Informed Consent
- Protocol and Amendments
- Investigator's Brochure
- Essential documents
- EU Directives & guidance documents

### Target group

Individuals who have recently started working in clinical research, either in the pharmaceutical industry or as investigational site staff or those who would like "a refreshment".

### Course leader

- Alistair Bone, Director of Quality Assurance and Training
- Sheelagh Corcoran, BSc, Global Training Manager

### 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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