

GCP Training - An Update On UK and European Regulations

This one-day course will provide all the latest information on the responsibilities of clinical trial personnel, guide delegates through the regulations and offer practical advice on how the regulations should be put into practice.

What Is The Course About?

This course will focus on the overall European legislation which provides the framework for all Member States but will also concentrate on the specific requirements for conducting clinical trials in the UK, which are laid down in the four UK Statutory Instruments. This course is aimed at anyone involved in clinical trials with medicinal products who would like an update on European and UK legislation. It will also distinguish between what is law and what is guidance on GCP.

By the end of this course, you will be familiar with:

- the latest developments in GCP and understand the effects that the Directives have on current working practices within clinical research
 - the Statutory Instruments that now form the UK regulations
 - Ethics Committees requirements and the changes in the UK ethics review process
 - the additional requirements within the Directive in relation to consent, especially for 'vulnerable groups' and 'Legal Representative'
 - the audit/inspection process and the importance of the mandatory inspections that are now being conducted at sponsor premises and investigational sites by the Medicines and Healthcare Products Regulatory Agency (MHRA)
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The Trainer

Joan Perou

Joan Perou, Hon. FICR is an acknowledged expert on Good Clinical Practice. Joan worked in the pharmaceutical industry for many years but became an Independent Consultant and Trainer on GCP in 2001. She now trains ethics committees, sponsor companies, academic institutions and government bodies on GCP. She was a Director of the Institute of Clinical Research for 6 years and when she left the Board in April 2008 she was made an Honorary Fellow to recognise her achievements.

Joan has conducted GCP courses in many countries and has written a number of articles on GCP which are used by universities in their coursework.

Course Fee: £599 +vat

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

For more information about this or any of our other courses or services, please call us on +44 (0)118 975 4512 or visit our website www.rostrumtrainingsolutions.com

Programme

GCP Training - An Update On UK and European Regulations

Introduction & Objectives

Background and Development of Good Clinical Practice

- European regulation
 - ICH and EU Directives 2001/20/EC and 2005/28/EC
 - What is guidance? What is law? - Clarifying GCP Regulation

The UK Regulations - Medicines For Human Use (Clinical Trials) Regulations

- The three Statutory Instruments that are legal requirements in the UK for everyone working on clinical trials with investigational medicine products:
 - SI 1031 - implemented 1st May 2004
 - SI 1928 - implemented 29th August 2006
 - SI 2984 - implemented 12th December 2006
- Including the important implications of the requirement for sponsors to report “Serious Breaches” of GCP at site to MHRA within 7 days.
- Introducing new Statutory Instrument 941, in force from 1st May 2008

Ethics Committees

- Directive requirements
- Update on the UK National Research Ethics Service (NRES)
- What is the additional R & D approval required at UK sites?

Informed Consent

- Directive requirements
- Legalities, process and documentation

Essential Documents

- The Data Trail
- Trial Master Files and Site Files - what documents should be kept and by whom?
- ICH Section 8 and Volume 10 Chapter 5 - spot the difference

GCP Inspection and Quality Issues

- Who are the Inspectors - and what are they looking for?
- Inspection preparation and survival!
- Feedback from recent inspections