

Introduction To Good Clinical Practice (GCP)

A beginners guide through the Regulation of Clinical Trials With Medicinal Products.

What Is The Course About?

This one day course is designed for newcomers to clinical research and will provide a basic overview of Good Clinical Practice regulation and processes. It will be of interest to anyone wanting information on Good Clinical Practice whether they are administrative or support staff or whether they are medically qualified and wanting to gain more information on conducting clinical trials with investigational medicinal products. This training day will focus not just on GCP regulation but on the practicalities of setting up processes and quality systems. The GCP Inspection process will also be discussed fully and findings from recent inspections will be used as examples of good and bad practice. Delegate inter-action is actively encouraged and there will be ample opportunity for question and discussion.

Course Objectives:

- To ensure that delegates have an understanding of the background and development of GCP and understand the concept as well as the regulatory framework.
 - To ensure delegates understand the current global regulatory environment, especially with regard to law and guidance.
 - To ensure delegates understand the role of the key players, investigators, sponsors, monitors and support staff and how important it is to work as a team
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The Trainer

Joan Perou

Joan is an industry renowned expert on GCP with over 20 years of international experience. Rostrum is very fortunate that Joan leads and designs several of our technical courses.

Joan's expertise covers a range of subjects and includes GCP, Audits and Fraud, documentation and Ethics Committees. Joan currently travels the world helping companies to understand and implement the EU Clinical Trials Directive and this enables her to deliver training that is technically correct and has a practical focus gained through real experience of what needs to be done to comply. Joan has helped many companies succeed in government audits to achieve compliance.

Joan is also a recognised expert on ethics committees and works closely with the NHS Executive to ensure that they are well trained, and in addition, Joan is also a member of National Working Group on Patient Information/Informed Consent.

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

Introduction To Good Clinical Practice (GCP)

Welcome & Introduction

The Clinical Research Process

Background & History of GCP

- ICH and the EU Directive on GCP in Clinical Trials

Protection of the Subject in Research

- Ethics Committees and Informed Consent

Essential Documents

- ICH Section 8
- FDA Documentation

Audit & Inspection

- Quality Issues

Responsibility of the Investigator / Monitor

- ICH requirements