

Clinical Trial Regulations

This course is an essential guide to ensure you comply with the regulatory requirements for carrying out clinical trials. Of specific interest to those departments who liaise with clinical trial personnel and all other professionals who want to know more about the regulations covering clinical trials.

What Is The Course About?

This course will cover all of the most important areas of regulations and guidelines controlling clinical trials. To ensure that clinical trials meet the requirements of the regulatory authorities it is essential that trials are carried out to the latest regulatory requirements. It is particularly important to keep up to date and be familiar with the recent developments in regulations for running clinical trials, and also how these are likely to impact on trials in the future for both pharmaceutical companies and the study sites.

This course covers:

- a comprehensive overview of the regulatory requirements for carrying out clinical trials
 - effective processes for obtaining Clinical Trials Authorisation - Regulatory and Ethic approval
 - the requirements for running clinical trials in children
 - the most important legal aspects of clinical trials
 - compliance in regulatory requirements for IMP, pharmacovigilance, EDC and e-source
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The Trainer

Dr Laura Brown

Laura is an independent training consultant and Director of the MSc in Clinical Research at Cardiff University. Laura has more than 18 years experience in the pharmaceutical industry. She has worked for several companies as a Clinical Research Manager, Audit Director and as Head of a Training Department.

Laura is an international expert on monitoring and Clinical Research issues. She was Chairman on the Institute of Clinical Research GCP Forum for six years, and writes regularly on clinical research and GCP.

She is a member of the Editorial Board of the Good Clinical Practice Journal and is author of SCRIP's latest GCP guide, and a practical guide to the Clinical Trial Directive.

Course Fee: £1,290 +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

Clinical Trials Regulations

DAY ONE

Introduction & Objectives

Overview Of The Framework Of Clinical Trial Regulations In Europe

EU Clinical Trials Directive And Some Of The Key Issues

The GCP Directive

Non-Commercial Guideline

Clinical Trial Authorisation : Regulatory Approval and Ethical Approval

Clinical Trial Regulatory Authorisation & Amendments

Running Clinical Trials In Children

Legal Aspects Of Clinical Trials

DAY TWO

Investigational Medicinal Product

Pharmacovigilance & Adverse Event Reporting

Clinical Trial Data Management Including EDC and E-Source

Other Recent Developments In Clinical Trial Regulations

FDA Recent Developments

Regulatory Inspection

Summary & Close