



clinical
research
facility
EDINBURGH

WTCRF
Education
programme



NHS
Lothian

Good Clinical Practice & the EU Directive A Half Day Update

Thursday 19th August 2010, 9.30am - 1:00pm

The Medicines for Human Use (Clinical Trials) Regulations 2004 now implement the EU Clinical Trials Directive (2001/20/EC) as law in the UK. This course is designed to provide an overview of the requirements of these regulations.

Research professionals involved in conducting clinical trials sponsored by NHS Lothian and the University of Edinburgh are required to demonstrate attendance at this course or demonstrate evidence of similar training.

Who will benefit from this course?

This course is relevant to individuals who have previously undertaken a GCP course and wish to update or re-fresh their knowledge. It is appropriate for anyone conducting or supporting clinical research. It is particularly suitable for those who are conducting or supporting Clinical Trials of an Investigational Medicinal Products (CTIMPs) and, as such, are required to provide evidence of having maintained and updated their knowledge of GCP. Attendance at the half day update course requires you to have undertaken GCP training within the past two years.

Course Outline:

Through a mixture of lectures and workshops this course covers:

- 1) Amendments to the regulations principles of GCP
- 2) Preparing for an MHRA inspection
- 3) Standard Operating Procedures - interactive session
- 4) Trail Master Files
- 5) Pharmacovigilance - series of case studies

Course Tutors: Dr Allan Gaw (MD, PhD, FRCPath, FFPM)
Director, Glasgow Clinical Research Facility
Shona McDermott
Education & Training Officer,
Glasgow Clinical Research Facility

Course fee: £30 (academic rate)

Venue: Wellcome Trust Clinical Research Facility,
Western General Hospital, Edinburgh

This course is recommended by NHS Lothian and University of Edinburgh

For more information, please contact:

Dr Jane Ilsley, Programme Manager, Wellcome Trust Clinical Research Facility, Western General Hospital, Edinburgh, EH4 2XU, Tel: 0131 537 3355,
E-mail: wcrf.education@ed.ac.uk

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