Brookwood International Academy

Fundamentals of Clinical Research & GCP

2007 Cert CRGCP Part 1 (Basic) Course

Day 1:

09.30 to 9.45
Introduction to course

9.45 to 10.45
The clinical development of a new pharmaceutical
Discovery, patents, generics, human pharmacology to therapeutic use studies in Phases I to IV and PMS, ICH new terminology.

10.45 to 11.00 Coffee Break

11.00 to 12.15
Basing a Clinical Trial on Good Science
Trial designs, randomisation, blinding, basic designs (with interactive exercises)

12.15 to 13.15 Lunch Break

13.15 to 14.15
Introduction to ICH Good Clinical Practice
What is GCP, why is it needed, development of US, European and ICH GCPs; the importance of working to SOPs. GCP Directive 2001/20/EC.

14.15 to 14.35 Coffee Break

14.35 to 15.50
ICH GCP in the critical path of a clinical trial
Presentation / Interactive exercise to determine steps in the critical path pf the trial and a discussion of GCP requirements

15.50 to 16.00
Recap, questions and discussion

Day 2:

09.00 to 10.15
How patients are protected in clinical trials
Declaration of Helsinki, ICH GCP requirements for Ethics Committees, informed consent and patient information.

10.15 to 10.30 Coffee Break

10.30 to 11.30
Pharmacovigilance: adverse event monitoring and reporting
Basic definitions and procedures ICH E2 documents.

Product accountability
Essentials of ICH GCP product accountability requirements

11.30 to 11.40 short break

11.40 to 12.15
GCP and the investigator
Training modules to enhance GCP compliance at the study site (PowerPoint shows)

12.15 to 13.15 Lunch Break

13.15 to 16.00
with Coffee Break at 14.30
Selecting investigators and performing initial site visits
Group work followed by presentations by groups and discussion. (Exercises 1, 2, 3)

- Dealing with laboratories
- Selecting the investigator
- Site assessment
- Pre-study briefing

Recap, questions and discussion

Day 3:

09.00 to 10.00
The collection and amendment of reliable data and the process of source data verification
The causes of unreliable data; the process of data monitoring and source data verification.

10.00 to 10.15 Coffee Break (and time to check out)

10.15 to 11.15
Routine monitoring visits
Group work (Exercise 4) Planning, preparation and execution of a routine monitoring visit.

11.15 to 12.15
The Trial Master File
The content of the TMF at sponsor and investigator sites (Learning by involvement session)

12.15 to 13.15 Lunch Break

13.15 to 14.00
Quality Assurance and audit findings, inspections by regulatory authorities
Audits and Inspections (national, European, US, Japan). Latest inspection policies and findings.

14.00 to 14.15
Recap, questions and close.

PO Box 9, Guildford, Surrey, GU3 2WZ, UK
Tel: +44 1483 811383: Fax: +44 1483 812163
Training with Certification (www.brookwoodacademy.org)