Brookwood International Academy

Essential GCP for Study Site Personnel

2007

SAMPLE PROGRAMME

Session 1

09.15 Introduction to course (5 mins)

Introduction to GCP
The importance of GCP in product development; globalisation of GCP requirements – the ICH process, principles of ICH GCP

Investigator Selection and Site Suitability
Requirements for subjects, facilities, time. The site assessment and log of study personnel

Study Protocol, Subject Recruitment
Agreeing the study protocol, protocol amendments, avoiding protocol violation

10.30 Break

Session 2

10.50 **Obtaining Acceptable Ethics Committee Approval**
GCP requirements for obtaining valid ethics committee approval

GCP and Informed Consent
Consent forms, subject information sheets, the consent process, dealing with consent form updates during the trial.

Collecting data, maintaining essential documentation, trial files
Completing and amending record forms: who and how? Log of subjects recruited. Source data and source data verification. *The essential documents, preventing premature destruction of critical information? Filing and archiving needs.*

12.15 Lunch

Session 3

13.15 **Management of investigational products**
Importance of product accountability, chain of use, code breaking rules, storage of drugs and other samples.

Dealing with Adverse Events
Definition of terms: adverse event, adverse drug reaction, expected/unexpected, reasonable causal relationship; how to report AEs, when and to whom.

14.15 Break

14.45 **Examination**
Optional examination for 'Certificate in Study Site GCP'
(takes approx 1 hour, multichoice exam)

A course designed and undertaken by
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An Academy dedicated to training and independent certification in clinical research and GCP