



Training Synopsis

COMPANY

Compliance Healthcheck Consulting UK Ltd

OFFICE

Kylen, Craigdarroch Drive,
Contin, Highlands, IV14 9EL, UK

PHONE

+44 (0) 1997 423311
+44 (0) 7909 111 510

EMAIL

stuart.mccully@chcuk.co.uk

WEB

www.chcuk.co.uk

Registered in Scotland - SC361237



GCP Refresher (UK)

COURSE TITLE: GCP Basics (UK)

COURSE CODE: GCP-R-UK-2012

COURSE DURATION: 3 hours

COURSE HANDOUTS: Colour presentation notes

NUMBER OF DELEGATES: Up to 15 delegates per course

COURSE COST: £1500*

WHO SHOULD ATTEND?

Anyone who is interested in, or involved, in the conduct of clinical trials in the UK and needs to 'refresh' their knowledge of the legislation and guidance

COURSE OBJECTIVES:

Re-familiarise participants with the historical basis for GCP
Illustrate & highlight the current GCP regulatory framework within the UK
Engage participants with practical case study examples of Good Clinical Practice
Provide participants with practical GCP knowledge
Highlight the main changes in the GCP regulations and guidelines in the past 2 years
Guide participants to useful GCP resources
Provide an open forum for discussion of best practice

COURSE OUTLINE:

Good Clinical Practice - A quick recap of the history behind the guidelines

- World War II
- Thalidomide
- Porton Down

Good Clinical Practice - European & UK Regulatory Framework

- The applicable UK Regulations and guidelines
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- The Research Governance Framework for Health and Social Care
- The MHRA, NRES and the HTA

Good Clinical Practice - What's new and what does it mean to me?!

A certificate of attendance will be issued to all participants who attend the training

* Course cost assumes
delivery of face-to-face
training at the clients' offices

