



## 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 Considerations for CRAs

**COURSE TITLE:** GCP Considerations for CRAs

**COURSE CODE:** GCP-CRA-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 interested in becoming a CRA or who has been a CRA for a few years and wishes to brush up on the practical considerations of being a CRA

### COURSE OBJECTIVES:

Explain the historical basis for the current good clinical practice (ICH GCP)  
Illustrate & highlight the GCP regulatory framework within Europe and the UK  
Familiarise participants with the GCP-specific terminology  
Engage participants with practical case study examples of Good Clinical Practice  
Highlight the roles and responsibilities required of CRAs by GCP  
Provide participants with practical GCP knowledge  
Guide participants to useful GCP resources

### COURSE OUTLINE:

Good Clinical Practice - The history behind the requirements

- World War II
- Thalidomide
- Porton Down

Good Clinical Practice - Monitoring

- Roles and responsibilities
- Monitoring and the 'applicable regulations and guidelines'
- ICH GCP Guidance (Section 5.18)

Good Clinical Practice - What does it mean to me?!

- Clinical trial conduct - From site initiation to archiving
- What to document and why
- Practical examples and case studies
- Common inspection findings
- The realities of being a Monitor

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

