



Training Synopsis

COMPANY

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GCP Refresher (Europe)

COURSE TITLE: GCP Basics (Europe)

COURSE CODE: GCP-R-EU-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 Europe 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 Europe
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
- The Tuskegee Syphilis Study
- Thalidomide

Good Clinical Practice - European Regulatory Framework

- Clinical Trials Directive (2001/20/EC)
- GMP Directive (2003/94/EC)
- GCP Directive (2005/28/EC)
- Data Privacy Directive (95/46/EC)
- From Directives to National Laws

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

