GCP Basics (Europe)

Training Synopsis

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Registered in Scotland - SC361237

COURSE TITLE: GCP Basics (Europe)
COURSE CODE: GCP-B-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 previously hasn't attended GCP training or hasn't attended in the last 5 years and wants specific guidance on the considerations for conducting clinical trials in Europe

COURSE OBJECTIVES:

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

COURSE OUTLINE:

Good Clinical Practice - 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 does it mean to me?!
- Clinical trial conduct (from start to finish)
- Specifics for Europe
- Archivist, what archivist?

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