GCP Considerations for Site Staff (UK)

Training Synopsis

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COURSE TITLE: GCP Considerations for Site Staff
COURSE CODE: GCP-Site-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?
This course is intended for UK site staff who are new to CTIMP and Non-CTIMP clinical research

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 Site Staff
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

Good Clinical Practice - Research Governance in the NHS
- What is GCP?
- The Research Governance Framework
- CTIMPs versus Non-CTIMPs

Good Clinical Practice - What does it mean to me?!
- Clinical trial conduct - From site initiation to archiving
- Roles & responsibilities
- The Trial Master File - What to document and why
- IMP management
- Informed consent
- Safety reporting
- Practical examples and case studies
- Common inspection findings

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