GCP Compliance and Research Governance

Training Synopsis

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COURSE TITLE: GCP Compliance and Research Governance
COURSE CODE: GCP-COMPLY-EU-2012
COURSE DURATION: 2.5 hours
COURSE HANDOUTS: Colour presentation notes
NUMBER OF DELEGATES: Up to 15 delegates per course
COURSE COST: £2500*

WHO SHOULD ATTEND?
Ideal for anyone in QA, clinical research project management and/or conduct, NHS R&D Departments, compliance and/or GCP training departments.

COURSE OBJECTIVES:
Explain the historical context for the current good clinical practice (GMP)
Illustrate & highlight the GMP regulatory framework within Europe and the UK
Familiarise participants with the GMP-specific terminology
Engage participants with practical case study examples of Good Manufacturing Practice
Highlight the clinical trial-related roles and responsibilities required by GMP
Provide participants with practical GMP knowledge
Guide participants to useful GMP resources

COURSE OUTLINE:
GCP - Compliance considerations
- Why bother?!
- What do you plan to do?
- What are the applicable regulations and guidelines?
- What systems do you have in place?
- Do they match?

GCP - Research governance and oversight
- Expectations, roles and responsibilities
- Quality Management Systems (QMS)
- Monitoring and audits

GCP Compliance - Practical considerations
- Research facilitation, not inhibition!
- Tell me what I need to do, before you tell me what I shouldn't do
- Compliance models
- Practical case study examples
- 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