GCP Considerations - GMP and the Regulatory Green Light (EU)

Training Synopsis

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COURSE TITLE: GCP Considerations - GMP and the Regulatory Green Light
COURSE CODE: GCP-GMP-RGL-EU-2012
COURSE DURATION: 2 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 clinical researchers who are already working on clinical trials and who wish to develop a greater understanding of the IMP-related aspects of GMP and the Regulatory Green Light (GMP)

COURSE OBJECTIVES:

Explain the historical context for the current good manufacturing 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:

Good Manufacturing Practice - Historical context
- Lash Lure
- Radithor
- Sulfanilimide
- Tylenol

Good Manufacturing Practice - European regulatory framework
- What is GMP?
- The regulatory framework
- The 'Qualified Person'
- The regulatory green light (RGL)

Good Manufacturing Practice - What does it mean to me?!
- From IMP release to destruction
- Annex 13 and IMP labelling
- Complaints and recalls
- 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