



E-LEARNING MODULE

GCP FOR INVESTIGATORS & STUDY SITE STAFF

As part of an overall library forming a complete training curriculum for Clinical Trials, J3I is pleased to present an e-learning module developed especially for Investigators and other Study Site Staff describing their responsibilities as specified in Good Clinical Practice (GCP). Julie Meeson of J3I has used her technical expertise in GCP, along with her considerable experience of many years of training to produce a module covering the following areas:

- Objectives and Definition of GCP
- GCP Legislative frameworks for USA, Europe and Global with interactive options
- Responsibilities of Investigators including:
 - Principles of GCP
 - Delegation, Oversight and Staff Qualifications
 - Resources
 - Informed Consent
 - Medical Care and Protocol Compliance
 - Investigational Product
 - Safety
 - Data, Records and Archiving

Sponsors are required to select Investigators who have sufficient GCP understanding and knowledge. Using this module, Sponsors can ensure that Investigators and Study Site Staff have detailed understanding of their responsibilities with regard to GCP. At the end of the module the user is automatically issued with a certificate to verify completion, which provides evidence to auditors and inspectors that GCP training has been provided. The running time of this multi-media training is approximately 25 minutes and allows optional user interaction to include sections as required. Using a combination of visual graphics and an audio narration, the user gains a near face to face training experience right from their desktop.

This e-learning module is designed to run in a standard Web Browser, is compatible with any operating system and can be run locally or over a network. Inter-operability with standard Learning Management Systems (LMS) is available, as is dedicated corporate branding if required, Also available are options for built-in competence assessments – please contact J3I to discuss your requirements.

For further details please contact J3I Limited:

Tel: +44 118 977 1736

E-mail: info@j3iquality.com

Web: www.j3iquality.com