E-LEARNING MODULE

GCP OVERVIEW

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 to provide an overview to 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, Definition and Principles of GCP
- Responsibilities of Sponsors, Investigators and Ethics Committees
- GCP Legislative frameworks for USA and Europe, including:
  - Code of Federal Regulations (CFR's) and FDA Guidance in the US
  - Regulations, Directives and Guidance in the EU
  - Clinical Trial, GCP and GMP Directives
  - Eudralex Volume 10 and GMP Annex 13
- Global Guidelines including:
  - ICH – Quality, Safety, Multidisciplinary and Efficacy Guidelines
  - Declaration of Helsinki / World Medical Association (WMA)

This module is particularly directed at Sponsor Staff who need to have a general awareness of GCP and its legislative frameworks. It is also ideal to provide an introduction to GCP for new employees. The running time of this multi-media training is approximately 20 minutes and it is designed to require no user interaction throughout its progression. 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 and certification – please contact J3I to discuss your requirements.

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