

E-LEARNING MODULE

UK CLINICAL TRIAL STATUTORY INSTRUMENTS

As part of an overall library forming a complete training curriculum for Clinical Trials, J3i is pleased to present an e-learning module providing detailed coverage of UK Statutory Instrument legislation most relevant to Clinical Trials with Investigational Medicinal Product. 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 in detail:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 – SI 2004/1031
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 – SI 2006/1928
- The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 – SI 2006/2984
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 – SI 2008/941
- The Medicines for Human Use (miscellaneous Amendments) Regulations 2009 – SI 2009/1164

The following SI's are also covered in outline:

- The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 – SI 2010/1882
- The Medicines (Advisory Bodies) (No. 2) Regulations 2005 – SI 2005/2754
- The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 – SI 2005/2759

This module is particularly directed at Sponsor Staff who are responsible for managing trials within the UK. The running time of this multi-media training is approximately 30 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.

For further details please contact J3i Limited:

Tel: +44 118 977 1736

E-mail: info@j3iquality.com

Web: www.j3iquality.com