

Course Details

This course is designed to provide comprehensive guidance and practical help for Clinical Project Managers, Clinical Research Associates and Quality Auditors on approaches to take in relation to selection, oversight, monitoring and audit of laboratories which undertake the analysis of samples from clinical trials.

The course will address the current regulatory framework for laboratory work conducted in support of clinical trials with reference to the ICH Guideline for Good Clinical Practice, the EU Clinical Trials Directive and other international related regulations and guidance. The course will also draw on the BARQA guidance document on Good Clinical Laboratory Practice (GCLP).

Who should attend:

- Clinical Project Managers
- Laboratory Managers
- Clinical Research Associates
- Clinical Quality Auditors
- Laboratory staff

Benefits include:

- guidance on the interpretation and application of GCLP within the framework of Good Clinical Practice (GCP)
- practical help on what to look for when selecting a clinical research laboratory for compliance with GCP and study requirements
- practical help on what to look for when overseeing clinical research laboratory activities
- Practical help on what to look for when monitoring or auditing a clinical research laboratory for compliance with GCP and study requirements
- an opportunity to improve delegates' understanding of the GCP requirements as they are applied in the laboratory
- an opportunity to update knowledge of GCLP with the current interpretation of requirements
- access to an experienced panel of speakers

Course Tutors

Tim Stiles

Director, Quality

Louise Handy

Manager, Peninsula College of Medicine & Dentistry

Madingley Hall, Cambridge 7th October 2008

Course Programme

Tuesday 7th October

9.15 Registration

9.30 Welcome and Introduction

9.45 **The GCP Regulations and their relevance to the Clinical Laboratory**

The current GCP regulations and how they apply to the laboratory, plus the different forms of accreditation that exist and their applicability.

10.05 **Laboratory Quality Management**

The scope, interpretation and application of Good Clinical Laboratory Practice as a quality system is explored. The importance of planning, logistics and analytical processes upon the quality and integrity of results are explained.

10.30 Break

10.45 **Selection of the Laboratory**

The primary reason for the selection of a particular laboratory should be its capability to perform the analysis required by the clinical protocol in accordance with GCP regulatory requirements. During this session we examine those areas which should be covered in order to assess such laboratories for compliance with GCP.

The areas to be covered will include but are not limited to:

- types of laboratories
- GCP awareness and compliance
- laboratory facilities
- laboratory accreditation
- contracts
- Quality Assurance
- laboratory experience
- capability and capacity
- location
- equipment availability
- proficiency schemes
- document retention capability
- quality system (including SOPs)
- sample retention
- analytical method
- results reporting standards
- validation/transfer
- staff experience
- qualification and responsibilities

12.30 Lunch

13.15 **Workshop**

I only have "five minutes" to visit the laboratory. What should I do?

13.45 **Workshop – Feedback and Discussion**

14.05 **Monitoring the Laboratory**

When visiting the analytical laboratory to monitor the conduct and performance of analytical work what should the monitor be looking for. During this session we present those areas which could be covered during the conduct of a monitoring visit to ensure compliance of the work which could include:

- project management
- work schedules and planning
- analytical plans
- kif preparation and sample shipment
- sample reception
- equipment operation and maintenance
- laboratory facilities
- definition of Raw/Source Data
- adverse event reporting
- CAPA
- data queries
- SDV
- reference ranges
- repeat sample analysis
- agreements and contracts
- results approval and reporting

15.30 Break

15.45 **Clinical Quality Assurance (Laboratory)**

Having selected an appropriate laboratory and conducted monitoring of a particular study, there are additional systems and procedures which could also be included with a review to ensuring the continued compliance of the laboratory. The areas to be covered during this session include but are not limited to:

- quality control
- internal quality audit
- training records
- laboratory staff
- documentation and sample retention
- archiving documentation
- external QA
- proficiency schemes
- equipment performance and calibration

16.30 **Panel Session**

This panel session will address any outstanding issues raised by delegates.

16.45 *Close of course*

Course Fees:

Association Members	£365 inc VAT
Non Members	£415 inc VAT

The Member rate is available, as a concession, to those working in relevant charities and academic institutions, or for the National Health Service.

Accommodation:

(Not included in course fees – please see booking form overleaf)

Accommodation, including dinner and breakfast, has been reserved at Madingley Hall for the night of Monday 6th October.

All bedrooms have en suite facilities.

