

Course Details

This course offers the ideal external training opportunity for those starting out as Quality Assurance auditors or working under Good Laboratory Practice regulation for the first time.

Benefits include:

- sound regulatory basis for quality assurance activities
- clear understanding of the role of Quality Assurance, Management and Study Director under the Good Laboratory Practice principles
- improved inspections and audits
- improved Good Laboratory Practice compliance for your facility
- an insight into government GLP monitoring activities

This course is structured to encourage delegates to:

- discuss and develop ideas
- solve specific problems
- examine particular aspects of GLP

Madingley Hall, Cambridge 11th-12th November 2008

Course Programme

Day 1 Tuesday 11th November

- 8.55 Registration
- 9.00 Welcome and Introduction
- 9.15 **Good Laboratory Practice Standards and Regulations**
An insight into the background and history of Good Laboratory Practice.
- 9.45 **Principles of Quality Assurance (1)**
The role and responsibilities of QA.
- 10.30 *Break*
- 10.45 **Principles of Quality Assurance (2)**
The role and responsibilities of QA.
- 11.30 **Study Plans**
GLP requirements and QA involvement.
- 12.05 **Standard Operating Procedures**
GLP requirements and QA involvement.
- 13.00 *Lunch*
- 14.00 **Inspections**
Attitudes, techniques and attributes.
- 14.40 **Workshop 1 – Facility and Process inspections**
An exercise in inspection planning and preparation for inspections.
- 15.15 *Break*
- 15.30 **Workshop 1 – Continued**
- 16.15 **Workshop 1- Feedback**
- 16.30 **Panel Session**
An opportunity for delegates to put questions to the panel of speakers.
- 17.15 *Close of day*
- 19.00 for 19.30 *Course dinner*

Day 2 Wednesday 12th November

- 9.00 **Workshop 2 – A Mock Audit**
- 10.45 *Break*
- 11.00 **Workshop 2 – Feedback**
- 11.30 **Auditing the Study Report**
Techniques and methods for the QA audit of the study report.
- 12.15 **The Management of Raw Data, Record Keeping and Training Records (1)**
 - the impact of GLP on data and records management
 - the use of computers in a GLP environment
- 13.00 *Lunch*
- 13.45 **The Management of Raw Data, Record Keeping and Training Records (2)**
- 14.15 **Workshop 3 – Amendments to Study Plan and Deviations from the Plan**
 - what are they?
 - what is the difference between them?
 - how are they controlled?
- 15.00 **Workshop 3 – Feedback**
- 15.15 *Break*
- 15.30 **Regulatory Compliance**
Government monitoring for compliance with Good Laboratory Practice.
- 16.15 **Panel Session**
An opportunity for delegates to put questions to the panel of speakers.
- 16.45 *Close of course*

Course Tutors

Roger Chapman
Director of Quality Assurance, LSR
(Course Principal)

Andrew Gray
GLP Operations Manager
Inspector, MHRA

Jane Wright
Associate Auditor,
Pfizer Global R&D

Course Fees:

Association Members	£750 inc VAT
Non Members	£910 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 nights of Monday 10th and Tuesday 11th November.

All bedrooms have en suite facilities.

