

Dates: 9th - 10th March 2010
Venue: Madingley Hall, Cambridge

This new, highly interactive course will provide state of the art guidance on how to implement quality systems into the research environment. The programme is delivered by leaders in the field who quite simply, "Have Done It". Whether you are at senior management level seeking strategic direction, a new lab head wishing to deliver science that will stand the test of time or a quality professional thrown in at the deep end, this course will provide key insight and practical guidance to underpin your future success. Based on phase appropriate systems, tried and tested over many years in the field, the programme will help you define, train, implement and monitor the quality of your research, irrespective of field or discipline. Position your organisation for the future success it deserves.

The benefits of the course are multiple. You get immediate access to highly experienced workers in this challenging field, who will share their experience and insight in an area where few others have been successful. Accordingly, you will be guided thoughtfully through each key component of the initiative in a stimulating learning environment crafted to deliver clarity from the onset. The course probes all avenues of the research quality arena, from an initial understanding of the cultural aspects of the scientific discovery environment, to how to manage quality in outsourced research programmes. Computer systems and e-data security in the research environment will be discussed in detail and pragmatic solutions described to help manage the ballooning cloud of e-data. In addition, the ever blurring boundary between the regulated and non regulated research environments will be discussed and delegates given perspective of future developments in the field.

The course is designed for all those involved in the research quality arena and has been tailored to meet the needs of scientific management, bench scientists and quality professionals alike. With this knowledge, you will get it 'Right First Time'.

Programme

Day One Tuesday 9th March

- 8.50 Registration
- 9.00 **Welcome and Introductions**
- 9.30 **History and Overview of the Field, Examples of Business and Regulatory Risks, Consequences of Low Quality in Research**
- 10.30 Break
- 10.50 **The Culture, the Politics, the Scientist's Perspective**
- 11.50 **What's out there already - Standards and Guidelines**
- 12.30 Lunch
- 13.15 **Group Breakout - What do you think are the Critical Success Factors for the Implementation of a Successful Quality System?**
- 13.45 **Debrief and Summary**
- 14.15 **Training - Get it Right First Time**
- 14.45 Break
- 15.00 **Implementation and its Challenges "If I have to do this I will have to stop my Science!"**
- 16.00 **End of day wrap up and debrief**
- 16.30 Close of day
- 19.00 for 19.30 Course dinner

Day Two Wednesday 10th March

- 9.00 **This highly interactive session will go through a compliance assessment programme in detail and will cover key topics including:**
 - Strategy Definition
 - Management Buy In
 - Preliminary Communications
 - Opening Meeting
 - Audit Scope and Requirements
 - Data Ownership Reviews and Data Selection
 - Archives and IT Infrastructure
 - Data Reconstruction Interviews
 - Updates
 - Escalation
 - Closing Meeting
 - Report Writing
 - Report Communication
 - Programme Iteration & Continual Improvement
- Q&A
- 12.30 Lunch
- 13.30 **Computer Systems in the Non-regulated Research Environment**
- 14.30 **Research Outsourcing & Quality - What Can Be Done**
- 15.15 **The Future**
- 15.45 **Conclusions and Wrap Up**
- 16.00 Close of course

Course Tutors

- Stephen Volsen** QA Auditor, Novartis Pharma AG
(Course Principal)
- Louise Handy** Head of Regulatory and Quality Affairs, OI Sciences Limited
- Marc Masson** Eli Lilly and Company
- Peter Esch** Senior Auditor IT Systems, Novartis Pharma AG

Course Fees

Association Members	£750
Non Members	£910
(all prices are in GB Pounds and include VAT at the standard rate).	

The member rate is available as a concession to those working in relevant charities and academic institutions or for the NHS. Concessions cannot be booked online. Please see the Terms and Conditions for more information.

Accommodation

(not included in course fees)

A. Dinner and accommodation on 8th March	£110
B. Course dinner and accommodation on 9th March	£110
C. Day Delegate including course dinner on 9th March	£45
D. Day Delegate (no course dinner or accommodation)	£0

All bedrooms have ensuite facilities

Venue
Madingley Hall, Cambridge

Date
9th - 10th March 2010

Please send to
BARQA
3 Wherry Lane
Ipswich IP4 1LG
Phone: +44 (0) 1473 221411
Fax: +44 (0) 1473 221412
Email: courses@barqa.com

Online booking
Alternatively, book online at
www.barqa.com

Additional booking forms
To download additional
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Information
For general information
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By signing this booking
form you are agreeing
to our current Terms and
Conditions.

Company limited by
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VAT no. 6386433 16



**The Research
Quality Association**

1 Delegate details

Please complete clearly with your booking and payment details and fax or mail to reserve your place on the course.

First Name

Last Name

Position

Organisation

Address

Post Code

Country

Telephone

Fax

E-mail

Special Requirements (diet etc.)

The above contact details will be used in the course delegate handbook unless you tick this box

Brief outline of the nature of your work and your experience relevant to this course

2 Booking details

(all prices are in GB pounds and include VAT at the standard rate)

Course Fees (select one option)

Association Members £750

Non Members £910*

Concessions £750

Accommodation Options (Select your options)

A) Dinner and overnight accommodation on 8th March £110

B) Course dinner and overnight accommodation on 9th March £110

C) Day Delegate including course dinner on 9th March £45

D) Day Delegate (No course dinner or accommodation). £0

TOTAL FEES £

*Includes the option of applying for membership of BARQA, free of charge, during the course.

3 Payment details

Credit Card

VISA MASTERCARD EUROCARD AMEX

Card Number

Expiry Date / Security code

Cheque
Made payable to BARQA (only accepted in GB Pounds drawn on a UK bank)

Bank Transfer
Please quote your name/invoice number as a reference and include ALL bank charges.
To Lloyds Bank, 99 High Street, Huntingdon, Cambridgeshire PE18 6DU, England
Account No. 01402840 Sort Code 30-94-47.

Invoice
Please invoice my organisation marking the invoice, for the attention of

and quoting purchase order no

Invoice address (if different to opposite)

Signature

Date