This course has been designed to provide you with the necessary skills and tools to prepare and host a regulatory inspection and to facilitate the response and follow-up to the inspection findings.

The course encompasses inspections at sponsor and contract research organisation sites, as well as at the investigator site.

Benefits include

- A clear understanding of the regulatory inspection process
- Practical experience of preparing for and hosting inspections
- Techniques for interpreting findings and observations and facilitating the preparation of effective responses
- Techniques for facilitating correction, corrective and preventive action arising from inspection findings

Who should attend

The course is designed for all those who will come into contact with the inspectors during a regulatory inspection and will be particularly useful for those given responsibility for preparing and hosting the inspection and managing the response process following the inspection:

- QA professionals
- Investigators
- Site managers

Course programme

Day 1 Wednesday 12th September

8.50 Registration

9.00 Welcome and Course Objectives

9.15 Basics and Background
- Introduction and background of GCP inspections in the major regions: EU, EMEA, FDA, MHLW, MHRA (and other EU MS)
- How active are the various national inspectorates
- Where do the different regulatory authorities inspect e.g. FDA in US and the rest of the world

10.00 Regulations
Standards the inspections are conducted against i.e. FDA CFRs, EU Directives, National regulations, ICH E6.

10.45 Break

11.00 FDA Preparation for Inspections

11.45 Inspection Support Strategy
- Level of QA support for inspections
- Contract Research Organisation (CRO)/sponsor/investigator site
- Accountability and responsibility at sponsor, CRO and site

12.30 Lunch

13.15 Workshop Discussion
Brainstorming session on strategies for inspection preparation, including specific challenges that may arise. Delegates are encouraged to raise topics of interest.

13.45 Inspection Preparation (on receipt of notification)
- Convene an inspection team
- Communications within the company
- Defining roles and responsibilities of team members
- Inspection training – what does this look like
- Preparation and submission of requested documents
- Select studies 'ripe' for the inspection and likely sites
- Logistics – book rooms, photocopier, etc.
- Communication with potential sites and support in preparation

14.45 Break

15.00 Inspection Conduct (during the inspection)
Sponsor/CRO
- Arrival – preparing security and reception personnel
- Document management/logging/control/copying
- Document review
- Dealing with multiple inspectors
- Check agenda, document request for the next day
- End of day summary from the inspectors
- Challenging findings and obtaining clarification
- End of day summary to company management

Site
- Document review
- Staff interviews
- Tour of facilities
- Pharmacy
- End of day summary from inspectors
- De-briefing of site staff

16.00 Interview Techniques
Presentation on interview techniques.

16.45 Panel Discussion, Review of the Day and Wrap-up

17.30 Close of day

Day 2 Thursday 13th September

9.00 Interview Practice Workshop
Role-play, small groups (4 or 5 – inspector, interviewee, scribe, QA) – sponsor/CRO and investigator sites.

10.15 Inspection Close-out Meeting
Determine up-front who should attend, who should document the observations, strategy for requesting clarifications.

10.45 Corrective and Preventive Action (CAPA) Developments and Lessons Learnt
Convene task force to do this following the exit meeting.

11.15 Break

11.30 Inspection Report
- Receipt of report
- Communication
- Examples of findings
- Definitions of severity used by inspectorates
- Consequences of inspections findings – especially if critical

12.15 Formulation of Responses
- How to respond
- Formulating responses – examples of good/bad
- What to do if you disagree with an observation
- Managing inspectors' expectations

13.00 Lunch

13.45 Response Exercise

14.15 Sustained Inspection Readiness
- Quality management system
- Documented inspection process
- inspection training
- Organisational documents
- Contracts and agreements
- Inspection and audit findings
- Quality awareness and GCP training

15.00 Break

15.15 Inspection Close-out, Follow-up of CAPA

15.45 Course Review and Follow-up

16.00 Close of course

Venue
ITC Grand Central Hotel, Parel, Mumbai, India

Date
12th-13th September 2012

Course tutors
Bruce Seymour-Taylor
Director, Seymour-Taylor Consulting Ltd (Course Principal)

Solomon Yimam
Assistant Country Director, FDA India Office - Clinical Research

Shehnaz Vakharia
Principal Consultant, Theraverity

Course fees

Association Members	**INR 33,000***
Non Members	**INR 40,300***

(All course fees are in Indian Rupees).

*Plus Service Tax 12.36%

Detach here

Venue
ITC Grand Central Hotel, Parel, Mumbai, India

Date
12th-13th September 2012

Please send to
Blackarrow Conferences

#1, Ground Floor,
Pelikan Apartment
Next to Gulmohar Garden
Yari Road
Andheri West
Mumbai – 400 061

Phone: +91-22-6534 6154
Email:
barqa@blackarrow-conferences.com

Information
This course is being run by Blackarrow Conferences

This booking form is a tax invoice for service tax purposes when a payment is made. Please retain a copy for reimbursement purposes.

No refunds or cancellations will be processed within 2 weeks of the event.

Cancellations must be in writing and will incur a 10% administration fee.

Substitutes are allowed at no cost.

BARQA™
The Research Quality Association

1 Delegate details

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

First Name

Last Name

Position

Organisation

Address

Postcode

Country

Telephone

Fax

Email

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.

Where did you hear about this course/BARQA (please be specific)?

2 Course booking details

C3507 12-13th September 2012

	Member	Non member
Course Fees	☐ **INR 33,000***	☐ **INR 40,300***

TOTAL FEES INR

**Plus Service Tax 12.36%*

3 Payment details

Cheque
I/we enclose a cheque for INR_____ in favour of Blackarrow Conferences and this should be couriered to the Blackarrow Conferences address opposite.

Bank Transfer
Bank: ICICI bank, Versova Branch, Mumbai
Account Name: Blackarrow Conferences
Account Number: 041205000449
IFSC: ICIC0000412

Signature

Date

Detach here