

Linking Pharmaceutical Quality and Pharmacovigilance Systems

The GMP QP and the PV QP
– How they should work together

Friday 2 October 2009
London Marriott Hotel Kensington,
London, UK

DBA

About This Course

- Companies across Europe are now finding themselves subject to Pharmacovigilance (PV) inspections by their competent authorities – GPvP inspectorates in the UK.
- The overstretched GMP QP now finds he/she is expected to work with another QP – the PV QP.
- This course is designed to simplify the situation and remove any confusion.
- This course will explain the legislative background and key guidelines
- Most importantly explain the ideal relationship or interface between the GMP QP and PV QP – on occasion this is even found to be an individual filling both roles!

What You Will Learn

- The legislative background for Pharmacovigilance
- The relationship between the PV QP and GMP QP

Who Should Attend

- GMP QPs
- PV QPs
- QA

Course Outline

What is Pharmacovigilance (PV)?

EU Legislation relating to PV

The UK PV monitoring system

The 'Purple' Guide – its legal status and contents

The roles and responsibilities of the PV QP

Areas of interface between the QMP QP and the PV QP

- How they should work together

Regulatory PV inspections

- Common inspection findings

A panel discussion session to experience specific issues

Your Tutors



Liz Allanson
David Begg Associates, UK

Former manager of the UK MHRA's GMP inspection team.

Liz has a thorough understanding of international regulatory expectations for pharmacovigilance.



Gary Rees
David Begg Associates, UK

Before joining DBA, Gary spent many years with Wyeth, where he rose to Vice President, Quality and Compliance for the European, Mid-East and African regions.

Gary has extensive experience with the challenges of 'global' QA/Compliance programmes, including pharmacovigilance.

An ideal mix of lectures and discussions

Like all David Begg Associate courses, this course will provide ample opportunity for discussion and debate.

Delegates will learn from each other as well as from the tutors and will definitely feel 'involved' in the learning process.

Booking Form

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Please reserve me a place on this course...

First/only delegate attending: £675.00 Plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £540.00 Plus 15% Value Added Tax (VAT)

Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments

Excludes: all hotel accommodation and dinners (see Hotel Accommodation section)

Course begins at 09.00 on Friday and finishes before 17.00

Please write clearly in BLOCK CAPITALS

Mr/Mrs/Miss/Ms/Dr First Name Surname

Job Title Company

Full Street Address

Post Code

Delegate Tel No Delegate Fax No Delegate Email

Accommodation: I require accommodation (please tick box) YES NO See Hotel Accommodation section for details

Please indicate any special needs (dietary/accommodation):

To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)

Card Number Expiry Date

Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of £776.25 (first/only delegate) or £621.00 (additional delegate(s) from same site) (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. Settlement must be received at least 10 working days prior to the course start date. A VAT invoice will be provided. VAT Reg No GB 927 3679 85. Under UK law all applications are subject to VAT irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. Cancellations within 25 working days of the course start date are subject to charges (see Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

Purchase Order number

Authorised Signature Date Cheque enclosed

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number

The programme and other information contained in this brochure are correct at the time of printing and are published in good faith. David Begg Associates reserves the right to make any changes which may become necessary.

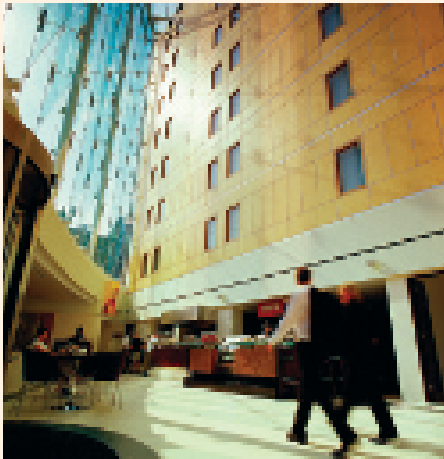
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The Venue

Located close to central London in the heart of Kensington, the London Marriott Hotel Kensington is one of the most contemporary hotels in London, a combination of superb, vibrant facilities and modern design with a stunning 7-storey atrium lobby. Retreat and recharge in the comfort of one of the guest rooms. The hotel also has high-speed internet access. Enjoy a great dinner in the fabulous new Fratelli Grill, or a selection of excellent martini cocktails and wines in the Nabuco Bar.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the London Marriott Hotel Kensington, at the specially negotiated room only rate of £189.75 (including VAT) per delegate per night.
- The night of Thursday 1 October will usually be reserved.
- Accommodation should only be reserved through us using the Booking Form. Credit card details must be provided to ensure this reservation is kept for you. Please do not contact the hotel directly as this could cause duplicate reservations.
- Your account with the hotel should be settled at check out.
- Any charges made by the hotel as a result of you not taking up your reservation for any reason will remain your responsibility.
- Where at all possible, your booking for accommodation should be received six weeks before the course start date. Places on the course will be available after this time but we cannot guarantee bedroom or rate availability.
- Where no indication is made on the Booking Form, no accommodation will be reserved by us.

To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form), confirming as above.

Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.