



IRISH MEDICINES BOARD



Continuing Professional
Development for
Qualified Persons &
Technical Personnel

Pharmaceutical Legislation Update

Wednesday 28 October 2009
Manchester Airport Marriott Hotel
Manchester, UK



About This Seminar

The Qualified Person and other Technical Personnel need to be informed and aware of pharmaceutical legislation. Changes in legislation and guidelines, and the interpretation of them, can have implications for the individual and their company.

This is the twelfth in a very successful series of one day seminars that are designed to form part of your Continuing Professional Development.

These are some comments from last year's course:

“Great snapshot of recent developments”

“A ‘one stop shop’ for keeping abreast of legislation”

“This is an essential element of my CPD”

What You Will Learn

- The reality and interpretation of recent and new EU legislation
- Changes to EU GMPs
- UK updates
- Quality Systems – update on ICH/International initiatives

Who Should Attend

Although designed primarily for Qualified Persons, these seminars provide rapid, efficient updates on issues of direct relevance to Technical Personnel in a broad variety of roles, including:

- Quality Management
- Production
- Engineering
- Regulatory Affairs
- Research & Development

Seminar Outline

- **Recent EU Directives and Regulations**
 - The reality and interpretation
 - QP responsibilities
- **EU GMP Changes: Updates and Discussions**
- **UK Developments**
 - MHRA news/inspections
- **International Developments**
 - Update on progress with ICH Q11 and IWG
- **US FDA Changes**

Why not bring your problems for discussion?

The seminar offers an ideal opportunity to speak to experienced tutors and to delegates who are in similar roles.

Our seminars are planned to inform you and also to enable you to gain answers to your specific queries via debate, group work sessions and a panel discussion.

Your Tutors



Peter Smith
David Begg Associates, UK

Peter Smith has nearly 40 years' experience in the pharmaceutical industry. He is also a former UK Regulatory Inspector.



Pete Gough
David Begg Associates, UK

Pete Gough has over 30 years' industry experience, including advising companies on how to best comply with new and impending legislation.

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, lunch and refreshments

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

Course begins at 09.00 and finishes at 16.00

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

The Manchester Airport Marriott Hotel is just five minutes by courtesy bus from the airport terminal buildings and railway station. Transport will also be available, free of charge, at the close of the course to take you from the hotel to your terminal building.

Situated adjacent to the M56 motorway, it is also easily accessible by road. With its comfortable bedrooms, swimming pool and fitness room, the hotel is an excellent place to relax as well as learn.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Manchester Airport Marriott Hotel, at the specially negotiated bed and breakfast rate of £122.34 (including VAT) per delegate per night.
- The night of Tuesday 27 October 2009 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.