

An NSF International Company

Q Qualified Person
& Professional
Development Training

Module 1

Monday 19 to Friday 23 October 2009
Hilton Hotel, York, UK

Pharmaceutical Law and Administration



University of
Strathclyde

Pharmaceutical Law and Administration

About This Course

Pharmaceutical law and administration is a key foundation knowledge requirement for all Qualified Persons (QPs). This is clearly spelled out in the relevant article of European Directives 2001/82/EC and 2001/83/EC and, closer to home, in the current UK Qualified Person Study Guide. The QP must ensure that the relevant laws are being complied with. Thus, a thorough understanding of the laws and legal processes, within Europe and beyond, is essential. This is equally true for other pharmaceutical technical managers.

This extremely popular module is designed to ensure that, in an increasingly changing world, you have a deep and detailed understanding of...

- Why we have medicines laws and what they seek to achieve
- The laws and legislative processes within the EU which impact on medicinal products, and hence the role of the QP
- The UK Medicines Act and legislative framework
- US and other international pharmaceutical legislation
- Other relevant laws and guidelines

Course Outline

European Medicines Legislation

- The legislative framework in the EU
- EU Directives affecting medicines
- Organisation and function of EMEA
- Rules governing medicinal products in the EU (EudraLex)
- Importation into the EU and distribution within the EU (wholesale dealing)
- Powers of the licensing authorities and adverse licensing reports
- Pharmacovigilance

UK Legislation

- Background and development of UK medicines legislation
- MHRA and VMD

Other Relevant Legislation

- US legislation and FDA
- International Conference on Harmonisation (ICH)
- PIC/S, WHO, etc

Reserve your place today email: qp@DBA-global.com



Course Tutors



Neil Wilkinson
David Begg Associates, UK



Pete Gough
David Begg Associates, UK



Peter Smith
David Begg Associates, UK

Plus other invited speakers from a regulatory consultancy and MHRA.

Discussion and Working Groups

A significant proportion of the course time will be devoted to group work, where delegates have the opportunity, through case studies, to put theory into practice.

Additionally, discussion periods, including a course tutor panel session, provide delegates with an opportunity to obtain answers to their specific questions and concerns.

Booking Form

Qualified Person & Professional Development Training - Series 10 Module 1 - Pharmaceutical Law and Administration

Hilton Hotel, York, UK

Monday 19 to Friday 23 October 2009

(Course begins at 09.00 on Monday and closes at 16.00 on Friday)

First/only delegate attending: **£3105.00** plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: **£2484.00** plus 15% Value Added Tax (VAT)

20% discount applies to second and subsequent delegates from the same site for this module

Includes: tuition, comprehensive course notes, attendance certificate, lunches, refreshments and course dinner on Thursday evening

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

| | |
|---------------------|-------------------|
| Surname | Mr/Mrs/Miss/Ms/Dr |
| First Name | Job Title |
| Company | |
| Full Street Address | |
| | |
| | Post Code |
| Delegate Tel No | Delegate Fax No |
| Delegate Email | |

Accommodation: I require accommodation Yes No

Please indicate any special/extra requirements (dietary/accommodation)

To guarantee your accommodation reservation, credit card details must be supplied

Card Number & Expiry Date (please write clearly)

Please Note: There are a limited number of rooms at the Hilton York Hotel which will be allocated on a first come first served basis. We will endeavour to hold rooms on your behalf up to 4 weeks before the start of the course but after that date we cannot guarantee bedroom or rate availability.

Cancellations: Please note that any charges imposed by the hotel as a result of you not taking up your reservation will remain your responsibility.

Course Fees: Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of **£3570.75** (first/only delegate) or **£2856.60** (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 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.

Date Purchase Order number

Cheque enclosed Yes No

Authorised Signature

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

David Begg Associates (York) Ltd

The Georgian House · 22/24 West End · Kirkbymoorside · York · UK · YO62 6AF

Tel +44 (0) 1751 432999 Fax +44 (0) 1751 432450

Email: qp@DBA-global.com Website: www.DBA-global.com

David Begg Associates (York) Ltd.

Registered in England & Wales No. 3432550 Registered Office 22/24 West End, Kirkbymoorside, York YO62 6AF

An NSF International Company

Why This Training Will Benefit YOU

The Aspiring Qualified Person

- This series of 12 modules held over a 21 month period has been carefully designed to meet the requirements for theoretical training detailed in the latest UK Qualified Person Study Guide and EC Directives 2001/82/EC and 2001/83/EC.
- All our training courses provide practical, face-to-face tuition in sufficient depth to prepare you fully for the challenges that lie ahead.
- Our training is generally considered as the best available and our QPs are held in high regard within the industry.
- As well as being accepted in the UK, our training courses are well known and accepted by several other EU countries, including Ireland, The Netherlands, Austria, Hungary and Malta.
- You are more likely to become a QP with us than with any other training provider!

The Pharmaceutical Technical Professional

- Not all the people attending these courses intend to become QPs. Many use the training to develop as technical managers within other areas of pharmaceutical manufacture and control.
- Increasingly, companies are using these modules as part of a modular technical and professional development plan for their staff.
- Additionally, many industry professionals attend the courses as part of their Continuing Professional Development.

To Book on this Course

- Fax the completed and signed form from this brochure to our QP 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.

The logo for DBA (Drug Business Association) is displayed in large, bold, orange capital letters at the bottom right of the page.



The Venue



The Hilton Hotel, York is conveniently located in the city centre and boasts 130 high-quality rooms, two popular restaurants and secure parking. The historic city of York has many attractions for visitors; the famous Minster, many museums, the Jorvik Viking Centre and excellent shopping. London is two hours away by train and there is a direct rail link to Manchester Airport. Leeds/Bradford Airport is also nearby.

Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Hilton York Hotel, at the specially negotiated bed and breakfast rate of £102.77 (including VAT) per delegate per night.
- The nights of Sunday 18 to Thursday 22 October 2009 inclusive will usually be reserved. We are happy to make a hotel reservation on your behalf up to 4 weeks before the course start but after that date we cannot guarantee bedroom or rate availability.
- 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 no indication is made on the Booking Form, no accommodation will be reserved by us.

Booking your place couldn't be easier!

Phone +44 (0) 1751 432999 **Email** qp@DBA-global.com

Fax +44 (0) 1751 432450 **Online** www.DBA-global.com

Post David Begg Associates (York) Ltd, The Georgian House, 22/24 West End, Kirkbymoorside, York, UK, YO62 6AF