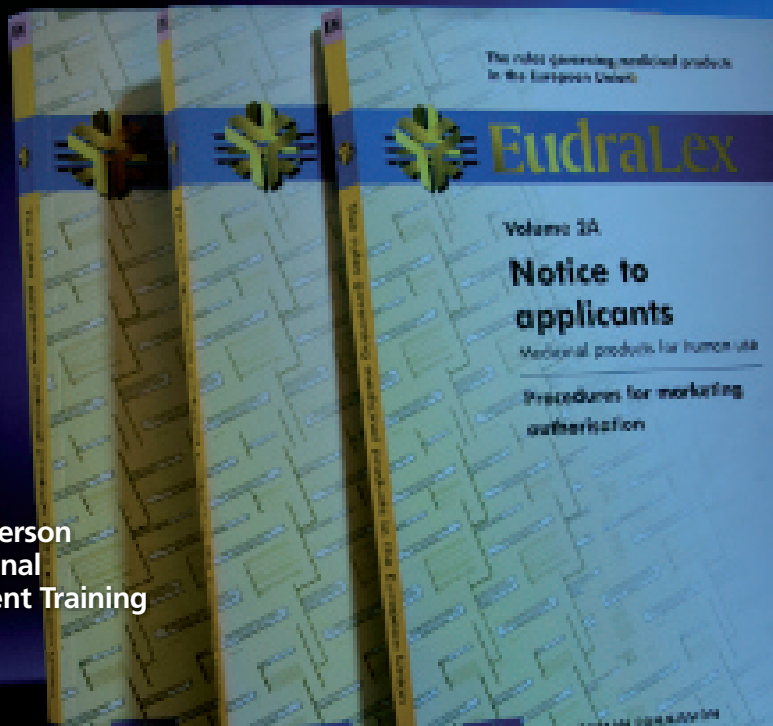


An NSF International Company



Q Qualified Person
& Professional
Development Training

Module 12

Monday 20 to Wednesday 22 July 2009
York Marriott Hotel, York, UK

The Role & Professional
Duties of the Qualified Person



University of
Strathclyde

The Role & Professional Duties of the Qualified Person

About This Course

The principle objective of this course is to emphasise how the QP should conduct themselves in discharging their legal duties.

Of paramount importance is the ability to focus on the broad issues of managing quality and to bring these issues together in a cohesive way when making decisions to certify medicinal products.

Throughout the course, therefore, delegates will have the opportunity to test their skills via interactive “release or reject” scenarios.

The course will also include a simulation of a typical UK QP interview as conducted by the three professional bodies.

Course Outline

The detailed legal and professional duties of the QP

- What can and cannot be delegated to others

The QP Code of Practice

- Implications for the QP

Current challenges facing the QP

- Recently implemented EU legislation and its implications

The role of the QP in complex manufacturing scenarios

- Annex 16 and beyond!

How to be an effective QP

- Influencing skills

Links with other functional groups

- The regulatory authorities and the inspectors

Product certification/release criteria

- The decision making process
- To certify or not to certify?

Routes to becoming a QP across the EU and the UK assessment procedure

- Education and training of QPs
- Simulation of a typical UK QP assessment interview procedure

The role of the IMP QP

- The particular risks and pressures for the QP releasing CT materials.

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



Course Tutors



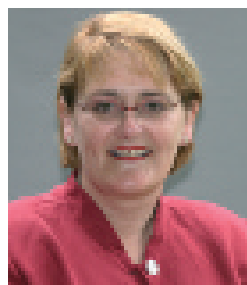
Pete Gough
David Begg Associates, UK

Pete is an experienced QP and is a former Chair of the Royal Society of Chemistry's QP Assessor panel.



Mike Russell
David Begg Associates, UK

Mike is an experienced QP and is the current Chair of the Institute of Biology's QP Assessor panel.



Erika Notman
David Begg Associates, UK

An experienced QP, Erika is a former Chair of the Institute of Biology's QP Assessor panel.

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 12 - The Role & Professional Duties of the Qualified Person

York Marriott Hotel, York, UK

Monday 20 to Wednesday 22 July 2009

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

First/only delegate attending: £1863.00 plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £1490.40 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 Tuesday 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 York Marriott 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 **£2142.45** (first/only delegate) or **£1713.96** (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 (Diploma in Business Administration) is displayed in large, bold, orange capital letters at the bottom right of the page.



The Venue



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.

Situated by the racecourse, just a short distance from the city centre, the York Marriott Hotel knows how to ensure you enjoy your stay. All rooms have air conditioning, multiple data points and phones with voicemail. There is ample free parking, full indoor leisure facilities, heated swimming pool and sauna.

Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the York Marriott Hotel at the specially negotiated bed and breakfast rate of £122.34 (including VAT) per delegate per night.
- The nights of Sunday 19 to Tuesday 21 July 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 bookings must be made direct to the hotel as we are unable to guarantee that accommodation will be available.
- 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