



IRISH MEDICINES BOARD



Continuing Professional
Development for
Qualified Persons &
Technical Personnel

Pharmaceutical Legislation Update

Tuesday 2 December 2008

Radisson SAS Hotel,
Dublin Airport, Ireland



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, and the first to be held in Ireland.

What You Will Learn

- The reality and interpretation of recent and new EU legislation
- Changes to EU GMPs
- UK and Irish 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**
- **Irish Developments/Concerns**
- **UK Developments**
 - MHRA news/inspections
- **International Developments**
 - Update on progress with ICH Q8(R1), Q10 and Q11
- **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.



Neil Wilkinson
David Begg Associates, UK

Neil is a chemist and has over 20 years' experience within the pharmaceutical industry, gained via a range of laboratory, quality management, manufacturing and supplier assurance roles, including wide experience within international roles covering the US, the EU and Asia. He has broad experience across a range of dosage forms and APIs, culminating in his previous role as Senior Director of Global Quality for AstraZeneca. Neil also has extensive experience of working with industry trade associations and was EFPIA topic leader within the ICH Q10 expert working group. Neil has acted as a QP and remains eligible to do so.

Plus an invited speaker from the Irish Medicines Board

Booking Form

Tuesday 2 December 2008
at the
**Radisson SAS Hotel,
Dublin Airport, Ireland**

Course Fee £725.00
pounds sterling

Pharmaceutical Legislation Update

**Continuing Professional Development
for Qualified Persons & Technical
Personnel**

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

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The programme and other information contained in this
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Accommodation: I require accommodation (please tick box)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	See <i>Hotel Accommodation</i> section for details			
Please indicate any special needs (dietary/accommodation):	<input type="text"/>					
To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)						
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<i>Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of £725.00 pounds sterling (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address above. Settlement must be received at least 10 working days prior to the course start date. VAT – the course fee is exempt from VAT which will be reflected on the invoice provided. 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.</i>						
Authorised Signature	<input type="text"/>	Purchase Order number	<input type="text"/>			
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The Venue

The Radisson SAS Hotel at Dublin Airport is a stylish contemporary hotel within the airport complex, where you will experience professionalism and friendliness during your stay. The hotel has been designed with the international business traveller in mind and offers a wide range of business facilities. Its location close to the M50 & M1 motorways and all the major road networks into Dublin makes it an ideal meeting location for not only airport passengers, but for guests travelling from around the country.

A 24 hour shuttle service from the airport provides a prompt transfer service for airport passengers. There is also a wide range of dining options available to guests from fine dining at Potters Restaurant to light refreshments in O'Dea's lounge.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Radisson SAS Hotel at the specially negotiated room only rate of €129.00 per delegate per night.
- The night of Monday 1 December 2008 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 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.