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EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

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



IRISH MEDICINES BOARD

Pharmaceutical Legislation Update



Wednesday 5 October 2011
Manchester Airport Marriott Hotel,
Manchester, UK



About This Course

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 significant implications for the individual and their company.

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

What You Will Learn

- The reality and interpretation of recent and new EU legislation
- Changes to EU GMPs
- UK updates
- An update on ICH/International initiatives
- USA changes to legislation and FDA guidance

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

Course 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 Q4 & Q11 and the IWG for Q8, 9 & 10
- **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.



Peter Smith
NSF-DBA, UK

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



Pete Gough
NSF-DBA, UK

Pete Gough has over 35 years' industry experience, including advising companies on how to best comply with new and impending legislation.

What Previous Attendees Said About This Course

"As always a 'one stop shop' for ensuring QPs keep abreast of new and upcoming legislation."

Angela White, Ipsen Biopharm Ltd, UK

"Very professional and easy style from the tutors makes the delivery of the detail and complex information easy to assimilate and understand."

Steve Whyard, Genzyme Ltd, UK

"Excellent course to get the flavour of new challenges."

Leonor Arrebola, Centocor BV, The Netherlands

"As good as ever, a great snapshot of recent developments."

Mark Sephton, Napp Pharmaceuticals Ltd, UK

"An excellent walk through of current and prospective pharmaceutical legislation, essential for CPD."

Neil Wayman, AstraZeneca Pharmaceuticals, UK

"Clear and concise presentations giving a good overview of current topics."

Daniel Bell, Napp Pharmaceuticals Ltd, UK

Booking Form

Pharmaceutical Legislation Update

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Manchester Airport Marriott Hotel, Manchester, UK

Please reserve me a place on this course...

First/only delegate attending: £695.00 Plus VAT at the prevailing rate (*where applicable – see note below*)

Additional delegate(s) from same site: £556.00 Plus VAT at the prevailing rate (*where applicable – see note below*)

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

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

The course begins at 09.00 and finishes at 16.00

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate; however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT PROVIDED THAT valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

VAT ID No.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT.

Mr/Mrs/Miss/Ms/Dr <input type="text"/>	First Name <input type="text"/>	Surname <input type="text"/>
Job Title <input type="text"/>	Company <input type="text"/>	
Full Site Address <input type="text"/>		
		Post Code <input type="text"/>
Delegate Tel No <input type="text"/>	Delegate Fax No <input type="text"/>	Delegate Email <input type="text"/>
Please indicate any special dietary needs <input type="text"/>		

Sterling cheques, payable on a UK bank to NSF-DBA Ltd, for the full invoiced amount (net of ALL bank charges) should be attached to this Booking Form and sent to NSF-DBA Ltd at the address below. A VAT invoice (if applicable) will be provided (VAT Reg No. GB 927 3679 85). Payments can also be made by bank transfer online (our company bank details are included on our invoice). Settlement must be received at least 10 working days prior to the course start date. Cancellations within 25 working days of the course start date are subject to charges (see Course Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

<input type="text"/>	Purchase Order number <input type="text"/>	
Authorised Signature <input type="text"/>	Date <input type="text"/>	Cheque enclosed <input type="text"/>

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. We reserve the right to make any changes which may become necessary.

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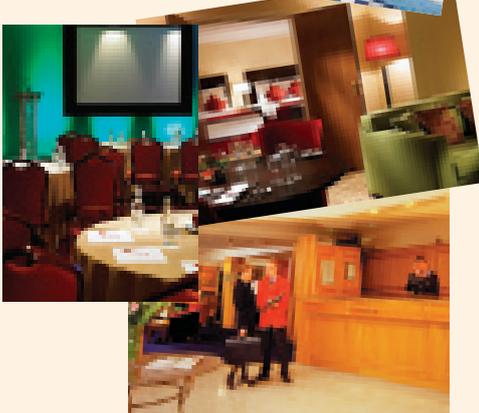
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The Venue

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

- We have a block booking of bedrooms at the Manchester Airport Marriott Hotel, at the specially negotiated bed and breakfast rate of £106.38 (plus VAT at the prevailing rate) per delegate per night.
- As part of our improvements to the booking process, we have arranged for an online booking service with the hotel and details of how to make your accommodation booking will be included in your course joining instructions (issued to you at the time of booking). Alternatively you will be able to make a telephone booking directly with the hotel. If you need any help or guidance with the accommodation booking process, please contact our course administration team.
- 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, therefore please ensure you are aware of the hotel's cancellation policy.
- Whilst places on the course will be available, we would also ask you to ensure that your booking for accommodation is made at least six weeks before the course start date as the hotel cannot guarantee bedroom or rate availability after this time.

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.

Course 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.