



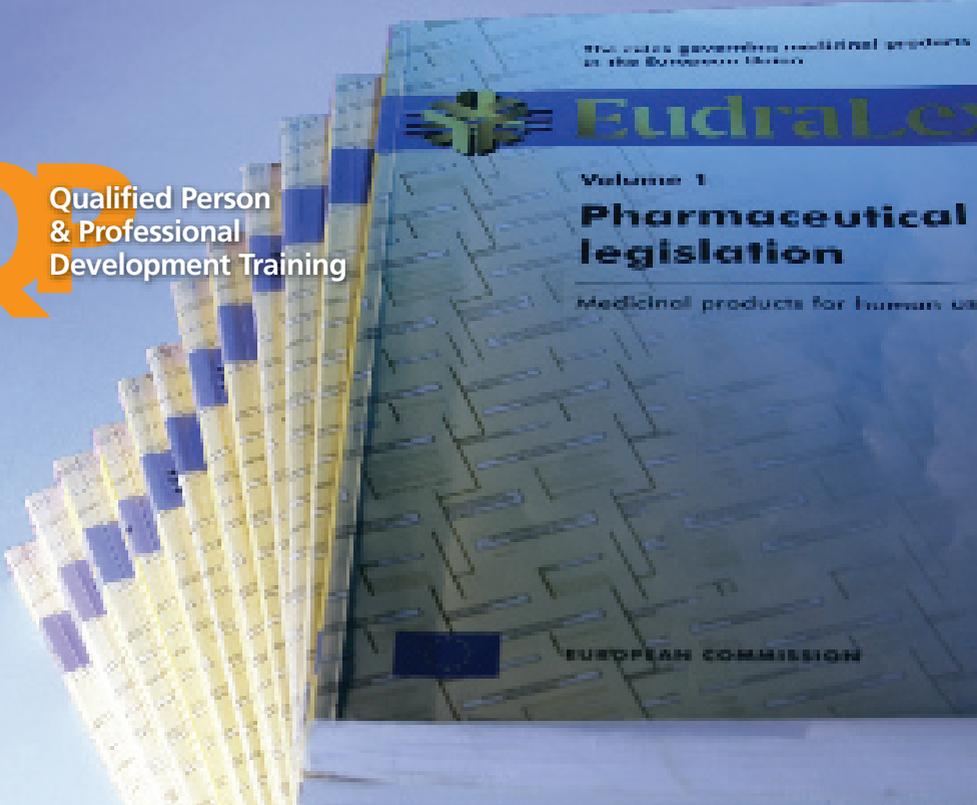
DBA

An NSF International Company

25 YEARS OF EXCELLENCE



Qualified Person
& Professional
Development Training



Module 3

Monday 17 to Friday 21 January 2011 & Monday 7 to Friday 11 March 2011
Hilton York Hotel, York, UK

Formulation & Processing



University of
Strathclyde

Formulation & Processing

About This Course

Once a new chemical entity has proved its potential in clinical studies, the challenge begins to formulate the compound into an effective medicine and to manufacture that medicine reliably so that safety, quality and efficacy are assured.

This module addresses the two important activities of formulation and processing and provides key information on...

- How the physico-chemical attributes of the drug and the therapeutic indication influence:
 - route of administration
 - dosage form
- Assuring bioavailability
- Methods of manufacture of the major dosage forms

- Factors affecting suitability for use of the major dosage forms

The Qualified Person, and other key technical personnel, **MUST** have a detailed understanding of these topics if they are to...

- Assist in the design and implementation of relevant, effective, quality systems for dosage form manufacture
- Contribute to the RISK ASSESSMENT process for processing changes and unplanned deviations
- Assess the adequacy of cleaning strategies
- Assess the potential impact of changes to physical and chemical attributes of starting materials

This, therefore, represents one of the key modules in this series.

Course Outline

WEEK 1

Formulation Issues

- Molecular properties of drugs and how these can influence metabolism, stability and biotransformation
- Pharmacokinetics
- Bioavailability
- Bioequivalence

Oral Dosage Forms - Tablets, Capsules, Liquids

- Major processing methods for solid dose, liquids and semi-solids
- Formulation challenges for the oral route of administration
- Critical process steps
- Key GMP requirements
- What goes wrong with the role of the QP

WEEK 2

Parenteral Products

- Routes of administration
- Formulation considerations
- Major processing methods
- Critical process steps
- Key GMP requirements

Inhalation Products

- The respiratory route of administration
- Formulation considerations
- Major processing methods
- Critical process steps
- Key GMP requirements

Topical Products

- The dermal route of administration
- Formulation considerations
- Critical process steps
- Key GMP requirements



Course Tutors



Mike Halliday
NSF-DBA, UK



Martin Lush
NSF-DBA, UK



Peter Gough
NSF-DBA, UK



Mike Russell
NSF-DBA, UK



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University of
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University of
Strathclyde



Simon Mackay
University of
Strathclyde



Alastair Davidson
University of
Strathclyde

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 11 Module 3 – Formulation & Processing

Hilton York Hotel, York, UK

Part 1: Monday 17 to Friday 21 January 2011

First/only delegate attending: **£3200.00** Plus VAT at the prevailing rate (where applicable –

Additional delegate(s) from same site: **£2560.00** Plus VAT at the prevailing rate see note below)

Part 2: Monday 7 to Friday 11 March 2011

First/only delegate attending: **£3200.00** Plus VAT at the prevailing rate (where applicable –

Additional delegate(s) from same site: **£2560.00** Plus VAT at the prevailing rate see note below)

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

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

Courses begin at 09.00 on Monday and close at 16.00 on Friday

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	First Name
Surname	Job Title
Company	
Full Site Address	
	Post Code
Delegate Tel No	Delegate Fax No
Delegate Email	

Please indicate any special dietary needs

Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount (net of ALL bank charges) should be attached to this Booking Form and sent to David Begg Associates (York) 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.

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.

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.

NSF-DBA trading as David Begg Associates (York) Ltd to 31 December 2010 then as NSF-DBA Ltd from 1 January 2011

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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.

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.





The Venue



The Hilton York Hotel 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

- We have a block booking of bedrooms at the Hilton York Hotel, at the specially negotiated bed and breakfast rate of £92.77 (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 using a special booking code which will also be included in your joining instructions. 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 four weeks before the course start date as the hotel cannot guarantee bedroom or rate availability after this time.

Booking your place couldn't be easier!

Phone +44 (0) 1751 432999 **Email** qp@nsf-dba.com

Fax +44 (0) 1751 432450 **Online** www.nsf-dba.com

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