

20TH  
SUCCESSFUL  
YEAR

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# Quality Aspects of the CTD

How to assure Flexibility, Practicality and Compliance

Monday 23 to Thursday 26 November 2009  
Hilton York Hotel, York, UK



**DBA**

# About This Course

The ever-increasing complexity of obtaining approval for drug products requires that companies provide high quality registration applications. To achieve this objective, it is essential that personnel in Regulatory Affairs, Research & Development, Manufacturing and Quality Assurance understand regulatory requirements and work together as an effective team.

The ICH Common Technical Document (CTD) has brought the possibility of a global dossier many steps closer. This emphasises the importance of getting it right first time.

David Begg Associates and Regulatory Resources Group have once again combined their complementary skills to present this well proven and successful course which is designed to provide attendees with a clear understanding of the regulatory process and technical data requirements for registration and subsequent manufacture of medicinal products. Although this course will primarily focus on EU aspects, consideration will be given to corresponding aspects in US submissions.

## What You Will Learn

- Current regulatory requirements and their impact on Chemistry and Pharmacy registration requirements:
  - Legal framework
  - CTD submission structure and content
  - Data requirements for new and established products
    - How much data is enough?
  - CTD summary documents
  - Role of the EU expert
  - EU marketing authorisation procedures
  - EU clinical trial applications
  - Post approval changes (variations)
  - GMP inspections
  - Role of the EU Qualified Person

## Who Should Attend

This course will be invaluable to:

- Regulatory Affairs professionals
- Quality Assurance and Compliance professionals
- Qualified Persons
- Data-providing professionals from:
  - Research & Development
  - Manufacturing
  - Document management

# Course Outline

- Legal framework for medicinal products
- CTD submission structure and content for new and existing products
- Data requirements for new and established products, with particular emphasis on:
  - Drug substance information, including drug master files and certificates of suitability
  - Pharmaceutical development including impact of ICH Q8
  - Manufacturing processes and validation/PAT
  - Control of excipients
  - Control of drug products – specifications, control methods and analytical validation
  - Container closure systems
  - Stability
- CTD summary documents
- The role of the EU expert
- EU marketing authorisation procedures
- EU clinical trial application requirements
- Post approval changes (variations)
- Manufacturing authorisations – for commercial and clinical trial products
- GMP inspections and regulatory compliance
- Risk Assessment in Regulatory Affairs
- Role of the EU Qualified Person:
  - Discretion when releasing batches
  - GMP declarations
  - Interface with Regulatory Affairs



# Your Tutors



**Liz Allanson**  
**David Begg Associates, UK**

Liz was formerly manager of the UK MHRA GMP inspectors. She has a wealth of knowledge on registration commitments and their impact on the manufacturing sites.



**Jenny Lamport**  
**Regulatory Resources Group**

Jenny was a founder of Regulatory Resources Group in 1990 and has been working in Regulatory Affairs in the pharmaceutical industry for more than 25 years.



**Pete Gough**  
**David Begg Associates, UK**

Pete Gough has over 30 years' industry experience, including advising companies on how to best comply with new and impending legislation.



**Helen Erwood**  
**Regulatory Resources Group**

Helen has worked within the pharmaceutical industry for more than 20 years. Helen brings to the course an enthusiasm for, and a broad experience in, global Regulatory Affairs.

**Plus other invited guest lecturers**

## Discussions and Working Groups

A significant proportion of 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

## Quality Aspects of the CTD

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Please reserve me a place on this course...

**First/only delegate attending:** £2210.00  Plus 15% Value Added Tax (VAT)

**Additional delegate(s) from same site:** £1768.00  Plus 15% Value Added Tax (VAT)

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

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

**Course begins at 09.00 on Monday and finishes at 15.00 on Thursday**

Please write clearly in BLOCK CAPITALS

Mr/Mrs/Miss/Ms/Dr  First Name  Surname

Job Title  Company

Full Street Address

Post Code

Delegate Tel No  Delegate Fax No  Delegate Email

Accommodation: I require accommodation (please tick box) YES  NO  See Hotel Accommodation section for details

Please indicate any special needs (dietary/accommodation):

To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)

Card Number  Expiry Date

*Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of £2541.50 (first/only delegate) or £2033.20 (additional delegates 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 at least 10 working days 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.*

Purchase Order number

Authorised Signature  Date  Cheque enclosed

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. David Begg Associates reserves the right to make any changes which may become necessary.

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# The Venue

The historic and beautiful city of York has many attractions for visitors; the famous Minster, many museums, Jorvik Centre and shopping areas. London's Kings Cross rail station is only two hours away. There is also a direct rail link with Manchester Airport. The city has easy road access from major motorways.

The Hilton York is a stylish 4-star hotel, conveniently located in the very centre of the city. The hotel boasts 130 rooms as well as two popular restaurants and, of course, excellent conference facilities.



## 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 22 to Wednesday 25 November 2009 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

Bookings cancelled up to 25 working days of the course shall receive a full refund. Cancellations received between 25 and 10 working days before the course shall receive a 50% refund. No refund will be given to cancellations received within 10 working days of the course start date. Delegate substitutions may be made at no cost at any time up to the start of the course.