

COST



TIME

Practical Aspects of Pharmaceutical Validation

Monday 22 to Thursday 25 March 2010
Manchester Marriott Victoria & Albert Hotel
Manchester, UK

DBA

About This Course

The regulators demand it, and it makes good business sense to do it, so why are companies still getting cited for:

- Failure to perform the necessary validations
- Validation studies inadequate

We will help you to avoid such criticism and provide sound, practical advice on key issues such as risk assessment to:

- Focus limited resources
- Set validation priorities

We will take you through the phased stages of qualification and validation to provide you with an appreciation of current industry best practice and a vision of the future for validation.

Meet like-minded colleagues, exchange views and benchmark your practice against current industry best practices.

What You Will Learn

- Current regulatory expectations for qualification and validation
- ICH Q8, Q9 and Q10 and the draft FDA Guidance on Process Validation: their future impact on validation
- How to plan, design, execute and document qualification and validation activities
- Specific validation expectations for a range of products, processes and systems
- How to maintain the validated status

Who Should Attend

The course will be particularly useful for staff from all parts of the pharmaceutical industry, including:

- Dosage form manufacture
- Clinical trials production
- API manufacture
- Research and Development

It is suited to staff from:

- Validation groups
- Quality Assurance
- Production
- Engineering

Course Outline

An Overview of Validation

- Qualification and validation explained

Regulatory Expectations for Validation

- EU and FDA expectations
- FDA's draft Guidance on Process Validation
- ICH Q8, Q9 and Q10
 - Implications for validation

Managing Validation

- A risk management approach to validation
 - using risk assessment to set priorities
- The Validation Master Plan
 - what to include and exclude
- The use of statistics in validation
 - experimental design – getting more from less!
- Dealing with deviations/validation failures
- Documenting qualification and validation

Validation Requirements for Specification Applications

- Qualification and validation of facilities and utilities
- Process validation for a range of dosage forms
- Cleaning validation
- Computer systems validation

Maintaining the Validated Status

- Linking change control to validation
- Requalification and revalidation

Presenting Validation Studies to the Regulators

- What to do and what **NOT** to do

Discussion and Working Groups

A significant proportion of the course will be devoted to group work, where delegates have the opportunity, through case studies, to put theory into practice.

Additionally, discussion periods will provide delegates with an opportunity to have their specific questions answered.



David Selby
David Begg Associates, UK

David has over 30 years' experience in the pharmaceutical industry. A recognised expert in the field of computer and software validation, David also has considerable expertise in the strategic planning and management of validation activities.



Peter Smith
David Begg Associates, UK

Peter is a former Specialist Principal Medicines Inspector with the UK Medicines Inspectorate. He also has extensive senior management experience within the pharmaceutical industry.

What Previous Attendees Said About This Course

"Plenty of food for thought! Excellent overview of an extremely important aspect of our industry – now to go back and challenge my colleagues!"

David Harvey, Reckitt Benckiser Healthcare (UK) Ltd

"I found it very useful and the use of real-life, practical examples really helped to illustrate the learning points"

Tara Dumigan, Almac Pharma Services, UK

"Introduction to Risk Assessment was brilliant"

Junad Ali, Recipharm Ltd, UK

"I'm very much impressed by the knowledge of the tutors and the everlasting energy that they had. I also enjoyed their sense of humour"

Arie Bokhorst, Solvay Biologicals BV, The Netherlands

"I feel that after the course I am qualified to do validation. It's really helpful for me to progress in my company"

Sivanandaswamy Matam, ColepCCL Industries Ltd, UK

"Good course – lots of information and useful course notes for future reference"

Anna Lomas, Genzyme, UK

Booking Form

Practical Aspects of Pharmaceutical Validation

Monday 22 to Thursday 25 March 2010

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Please reserve me a place on this course...

First/only delegate attending: £2275.00 Plus VAT at the prevailing rate

Additional delegate(s) from same site: £1820.00 Plus VAT at the prevailing rate

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

Excludes: all hotel accommodation and 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 Site 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 (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 Manchester Marriott Victoria & Albert Hotel stands on the banks of the River Irwell, near the city centre but convenient for Manchester Airport (19km), the city's Piccadilly rail station (3km) and the UK's motorway networks. Recently lovingly restored, this Grade II listed building bears many modern features. The hotel has its own car park and the Living Well Health Club with pool, gymnasium, sauna and steam room is just a few minutes from the hotel. Also nearby are the Imperial War Museum North West, Lowry Museum and Manchester's three theatres. A few minutes' walk takes you to the city's main shopping and eating district.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £107.22 (plus VAT at the prevailing rate) per delegate per night.
- The nights of Sunday 21 to Wednesday 24 March 2010 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 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.