



www.DBA-global.com

Pharmaceutical GMP

“Europe’s Most Popular GMP Course!”

Monday 17 to Thursday 20 May 2010
Manchester Marriott Victoria & Albert Hotel
Manchester, UK

DBA

About This Course

It is a legal requirement that all staff receive regular training in Good Manufacturing Practice.

This course is designed to provide you with up-to-date knowledge of new and impending GMP regulations and current “hot topics”.

Europe's Most Popular GMP Course!

- In the last seven years, over 850 delegates from all over Europe have attended this very popular course
- This course repeatedly achieves the highest customer satisfaction level of any of our courses, with 95% of delegates rating it “very good” or “excellent”

Delegates on a previous GMP course said:

“I found this course very interesting and useful. To me GMP is a new topic, which will be very important in my work as a future QP. Although the department wasn't very big, I think it was very useful to me to hear about all the different topics involving GMP. I want to thank the tutors for all the information they've given us. They did it in a very enthusiastic way and they have a lot of knowledge! Thanks and I'm looking forward to another DBA course!”

Roumaynes Schepers, Sandoz

“The standard of Lecturers/Presenters was excellent, very impressed with the quality and completeness of the material covered”

Gerard Kemmy, Covidien

“Really great tutors answering all our questions. Absolutely nice mix of lectures and buzz group working. The course had great content (for starters) and was very well presented”

Hans-Juergen Franke, B Braun

“Complete overview on GMP – that was what I was looking for. Regained my motivation to continue working in QA”

Markus Schoester, Novartis

“It is a fun and relaxed way of knowing much more about GMP”

Elma Snýder, Solvay

“Lecturers were very knowledgeable and presentation style was very good”

Nick Hodgson, Genzyme

Course Outline

A clear comparison of EU and FDA GMP requirements...

- Areas of agreement
- Critical differences

Up-to-the-minute information on new GMP initiatives and regulations...

- FDA's cGMP for the Twenty-First Century
- Changes to EU GMP regulations...
 - Product Quality Review
 - Ongoing Stability Testing
 - Reference samples and retention samples
- ICH Q9: Quality Risk Management

Practical advice on dealing with the “difficult areas” of GMP...

- Change Control
- Deviations
- Assessing the effectiveness of training

An understanding of how GMP is influenced by...

- Premises
- Processes
- Products
- Procedures
- People

An appreciation of the critical GMP issues for...

- Solid dosage forms
- Sterile products
- Liquids/semi-solids
- Packing operations
- Computers

A panel discussion session to explore **YOUR** specific GMP problems

Your Tutors



Liz Allanson
David Begg Associates, UK

Former manager of the UK MHRA's GMP inspection team.

Liz has a thorough understanding of EU and US GMP regulations.



Mike Halliday
David Begg Associates, UK

Former Associate Director, Global Audit and Compliance, Wyeth Europa.

Mike is experienced in interpreting EU and US GMP regulations in a practical manner.

Plus invited guest speaker

An Ideal Mix of Lectures, Discussions and Team Tasks

Like all David Begg Associates courses, this course will provide ample opportunity for discussion and debate.

Teamwork exercises will encourage participation and reinforce the messages of lectures and tutorials.

Delegates will learn from each other as well as from the tutors and will definitely feel “involved” in the learning process!

Booking Form

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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 16 to Wednesday 19 May 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.