



www.DBA-global.com

Pharmaceutical GMP

“Europe’s Most Popular GMP Course!”

Monday 15 to Thursday 18 December 2008

Amsterdam Marriott Hotel,
Amsterdam, The Netherlands

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 five years, nearly 700 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:

"Great course, extremely valuable and well paced. Relatively dry subject made stimulating and thought provoking."

Careen Snadden, Alliance-Unichem

"The course does a great job at giving a broad overview and as such very valuable to me. One of the best courses I've been on in my professional career!"

Thomas Chattaway, UCB-Bioproducts

"Feedback from the tutors excellent. Made GMP interesting again for me."

Declan Hoare, Athlone Pharmaceuticals

"Course was organised very well to facilitate interaction."

Inese Ozolina, Abbott Laboratories

"Very enthusiastic tutors, very interesting, good distribution between lectures and group assignments."

Frederick Lundberg, Pec A/S

"This course really exceeded my expectations. I have got a really good understanding on many processes. I am full of new ideas – I only hope I will be able to put one or two into practice."

Michaela Margetich, InterCell

"Very much enjoyed the course. Tutors were excellent and particularly liked the "real" life examples used during the lecture."

Anthony Pettigrew, Lifecycle Pharma

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.



Graham Davison
David Begg Associates, UK

Former Quality Assurance Director with Roche.

Graham has extensive experience of applying international GMP requirements to a range of dosage forms.



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.

An Ideal Mix of Lectures, Discussion 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

**Monday 15 to Thursday 18
December 2008**
at the
**Amsterdam Marriott Hotel,
Amsterdam, The Netherlands**

**Course Fee £2310.00
(pounds sterling)**

Pharmaceutical GMP

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

David Begg Associates (York) Ltd

The Georgian House,
22/24 West End, Kirkbymoorside,
York, UK, YO62 6AF
Tel +44 (0)1751 432999
Fax +44 (0)1751 432450
Email: courses@DBA-global.com
Online: www.DBA-global.com

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.

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 **£2310.00 pounds sterling** (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address above. Settlement must be received at least 10 working days prior to the course start date. VAT – the course fee is exempt from VAT which will be reflected on the invoice provided. 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.*

Authorised Signature Purchase Order number

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 Venue

The Amsterdam Marriott Hotel is among the superior hotels in Amsterdam, it offers an ideal location across from the Leidseplein's fine shopping, dining and entertainment. As a guest, you'll find well appointed guest rooms with high speed internet to keep you in touch. A well equipped fitness room will help keep you in shape. Fine dining awaits in their two restaurants.

Marriott
AMSTERDAM



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Amsterdam Marriott Hotel, at the specially negotiated bed and breakfast rate of €199.00 per delegate per night.
- The nights of Sunday 14 to Wednesday 17 December 2008 inclusive 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 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.