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# Pharmaceutical GMP

“Europe’s Most Popular GMP Course!”

**Monday 21 to Thursday 24 September 2009**

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 six years, over 750 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

***“Many good practical examples from the real world. Really good and impressive amount of experience represented. Good humour!”***

Hanne Jespersen, Nycomed

***“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-Bioproducs

***“Feedback from the tutors excellent. Made GMP interesting again for me.”***

Declan Hoare, Athlone  
Pharmaceuticals, Ireland

***“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

***“Didn't think I'd enjoy the course as much as I did. David Begg Associates has managed to make a 4-day GMP course a fun and enjoyable learning experience. The tutors all had great personalities and enthusiasm and really knew how to use their voices and language to deliver a course to a multi-national attendee list. Thank you!”***

Shivani Balasuntharam,  
GlaxoSmithKline

# 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, 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

## Pharmaceutical GMP

Monday 21 to Thursday 24 September 2009

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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 delegate(s) 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.

**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 Website: www.DBA-global.com

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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 £123.31 (including VAT) per delegate per night.
- The nights of Sunday 20 to Wednesday 23 September 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

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.