



# How to Perform Effective Product Quality Reviews

**Tuesday 27 October 2009**  
Manchester Airport Marriott Hotel,  
Manchester, UK

**DBA**

# About This Course

On 1 January 2006 the EU implemented a change to Chapter 1 of the EU GMP Guide to add the requirement to produce a regular Product Quality Review. This listed numerous criteria which should form part of that review.

The FDA has long required product reports to be submitted for licensed products and ICH Q7a, GMP for Active Pharmaceutical Ingredients, also requires that “processes should be periodically evaluated to verify that they are still operating in a valid manner”.

This course is designed to assist you and your company in producing Product Quality Reviews which meet these GMP expectations in an efficient manner that will add VALUE to your business as well as compliance to your operations.

## What You Will Learn

- The regulatory requirements for medicinal products and Active Pharmaceutical Ingredients in the EU and USA
- The data that should be included in a Product Quality Review and what may be excluded
- Statistical techniques to enable you to analyse and interpret data effectively
- How to decide if a process is in control, capable and still valid
- How to produce Product Quality Review reports which add value to your business and meet all regulatory expectations

## Who Should Attend

This course is for anyone involved in the...

- Design
- Preparation
- Review
- Approval
- Review of data

of Product Quality Reviews for medicinal products or Active Pharmaceutical Ingredients.

This will include...

- Qualified Persons
- Other quality personnel
- Laboratory staff
- Validation and technical staff
- Production staff
- Support specialists
- Regulatory Affairs professionals

# Course Outline

## Periodic Product Reviews

- What they are and why they are important
- Current regulatory expectations:
  - EU GMP Chapter 1
  - US CFR 21
  - ICH Q7a
- Data requirements

## Data Analysis Techniques

- Control charts
- Process capability
- Linear regression

## Data Interpretation

- How to identify trends in, and draw conclusions from, data

## Product Review Reports

- How to present the information
- How to document conclusions

## Acting on the Information

- How to make the exercise add value to your business

## Why not combine this with Pharmaceutical Legislation Update?

On Wednesday 28 October we shall be running a seminar which offers an ideal opportunity to speak to experienced tutors and to delegates who are in similar roles.

Why not stay an extra night and attend both these courses?

## Your Tutors



**Peter Smith**  
**David Begg Associates, UK**

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



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

Before joining DBA, Pete held numerous senior management positions within the pharmaceutical industry, culminating in his role as Senior Quality Consultant in Eli Lilly's Global Quality Systems division.

### **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.

# Booking Form

## How to Perform Effective Product Quality Reviews

Tuesday 27 October 2009

Manchester Airport Marriott Hotel, Manchester, UK

Please reserve me a place on this course...

**First/only delegate attending:** £675.00  Plus 15% Value Added Tax (VAT)

**Additional delegate(s) from same site:** £540.00  Plus 15% Value Added Tax (VAT)

**Includes:** tuition, comprehensive course notes, attendance certificate, lunch and refreshments

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

**Course begins at 09.00 and finishes at 16.00**

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 £776.25 (first/only delegate) or £621.00 (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 Airport Marriott Hotel is just five minutes by courtesy bus from the airport terminal buildings and railway station. Transport will also be available, free of charge, at the close of the course to take you from the hotel to your terminal building.

Situated adjacent to the M56 motorway, it is also easily accessible by road. With its comfortable bedrooms, swimming pool and fitness room, the hotel is an excellent place to relax as well as learn.



## Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Manchester Airport Marriott Hotel, at the specially negotiated bed and breakfast rate of £122.34 (including VAT) per delegate per night.
- The night of Monday 26 October 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 10 and 25 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.