



# GMP for Clinical Trials Manufacture and Supply

**Monday 19 to Thursday 22  
October 2009**  
Manchester Marriott Victoria & Albert Hotel  
Manchester, UK

**DBA**

# About This Course

The implementation of Directive 2001/20/EC has brought profound changes to the way clinical trials are conducted in the EU and equally important changes to the way IMPs are manufactured and controlled.

Few people within the pharmaceutical and healthcare sectors would question the wisdom of greater uniformity of approach to the conduct of clinical trials in Europe, but the application of the Directive is proving to be a significant challenge to manufacturers of clinical supplies...

- What 'standard' of GMP is appropriate at the various clinical trial phases?
- Validation – how much, how soon?
- What exactly is a Product Specification File?
- In the case of split manufacture, whose QP should release?
- What is the role of the QP when IMPs are imported?
- Where does GMP end and GCP begin?

All of these questions and many more will be addressed in this intensive four-day training course.

## What You Will Learn

- Current EU and US GMP regulations and expectations for the manufacture of IMPs
- How to apply these GMP expectations in a scientifically sound and cost-effective manner in the best interests of...
  - your company
  - the clinical trial volunteer
- The role of the QP in clinical supplies manufacture and the current position on QP discretion

## Who Should Attend

This course is primarily intended for those people working in the late stages of product development and all aspects of clinical supplies manufacture, packing and control.

It will therefore appeal to...

- Development scientists
- Regulatory affairs professionals
- Bulk API manufacturers
- IMP production staff
- Clinical supplies labelling and packing staff
- Quality control scientists
- Engineering staff
- QPs for IMPs
- Suppliers of contract services

In addition, the course will also be of value to existing QPs and trainee QPs wishing for a new role in the certification of IMPs.

*Please contact us if you are unsure of the suitability of this course for your needs.*

# Course Outline

## The Clinical Trial

- Phases of clinical trials
- Impact of trial design on manufacture and packing

## Directive 2001/20/EC

- Detail of the Directive
- Implications for manufacture, labelling, packing, control and release of IMPs

## Annex 13

- Detail of the revised Annex
- How the Annex can be applied in a scientifically sound and cost-effective way

## EU and FDA Regulations Compared

### GMP Issues for Premises

- What the guidelines say
- Equipment qualification
- Cleaning

### Control of Starting Materials

- Specifications
- GMP for storage areas
- Sampling plans
- Release procedures

### GMP Issues for Active Ingredient Manufacture

- Applying ICH Q7
- Challenges of scale-up

### Manufacture of the Dosage Form

- Blinding issues
- Manipulation of comparators
- Quality Control

## Labelling and Packing Issues

- Control of packaging components
- Control of label printing
- Strategies to avoid mix-ups
- Blinding issues
- Label text requirements
- Reconciliation
- Stability testing/expiration dating

## Validation Issues

- How much, how soon
- Cleaning validation or verification
- Analytical method validation

## Documentation Issues

- Batch records
- Notebooks vs pre-printed forms
- IMP dossier
- Product Specification File
- Control of documentation

## Release Procedures and the Role of the QP

- Two-stage release process
- Role of the QP
- Split manufacture and virtual companies – who is responsible

## Change Control

### The GMP/GCP Interface

- Relabelling
- Site-to-site transfers
- Complaints and recalls
- Dealing with returns

## 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 including a tutor-led panel session will provide delegates with an opportunity to have their specific questions answered.

## Your Tutors



**Liz Allanson**  
**David Begg Associates, UK**

Former manager of the UK MHRA's GMP inspectors with extensive experience of applying the current EU regulations to the manufacture of clinical supplies.



**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 Russell**  
**David Begg Associates, UK**

Mike has held QA management positions with Roche, Centocor and Cambridge Antibody Technology Ltd. He has broad experience of clinical trials manufacture and is a QP assessor for the Institute of Biology.

**Plus invited speakers**

# Booking Form

## GMP for Clinical Trials Manufacture and Supply

Monday 19 to Thursday 22 October 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 · Y062 6AF

Tel: +44 (0) 1751 432999 Fax: +44 (0) 1751 432450 Email: courses@DBA-global.com Website: www.DBA-global.com

David Begg Associates (York) Ltd. Registered in England & Wales No. 3432550 Registered Office 22/24 West End, Kirkbymoorside, York YO62 6AF An NSF International Company

# 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 18 to Wednesday 21 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 25 and 10 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.